The Use of Qualitative Risk Analysis Methods to Facilitate Decision Making in the Management of Health and Welfare in Wildlife.

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Matthew Hartley

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“The material being presented for examination is my own work and has not been submitted for an award of this or another HEI except in minor particulars which are explicitly noted in the body of the thesis. Where research pertaining to the thesis was undertaken collaboratively, the nature and extent of my individual contribution has been made explicit.”

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Abstract

This thesis is composed of a series of papers, all of which have been published in peer reviewed publications. The papers use the recognised process of qualitative risk assessment in a range of scenarios in the field of wildlife health and welfare in both in situ and ex situ environments. Chapter 1 discusses the challenges faced regarding availability of empirical data in field of wildlife and zoological health and welfare and justifies the exploration of techniques to assist with decision making. The development of risk analysis and its integration with risk management and risk communication to become risk assessment is described before being put into the specific context of wildlife and zoological disease.

Chapters 2 and 3 consider two scenarios where disease risk assessment is well established as a tool, importation across national borders and in conservation interventions. Chapter 2 develops the standard import risk assessment approach to include multiple species and multiple diseases. Chapter 3 reviews developments made over the last 25 years and proposes best practice approaches to implement. Chapter 4 describes how the risk assessments formulated as described in Chapter 3 are used for licensing purposes emphasising the importance of risk management and communication. This theme is continued in Chapter 6 where the integration of risk assessment and evidence based decision making is considered in the broad context of a strategic approach to wildlife health bringing together the outcomes and processes described in Chapters 2, 3, 4 and 5.

The papers in Chapters 2,5 and 8 are focused on how risk analysis aids in development of disease control approaches and policy. The evidence base is composed primarily of peer-reviewed literature supported by expert review of the finalised assessment. Chapter 7 uses risk assessment in an applied scenario, taking the recognised process and modifying it to structure an active disease investigation demonstrating the versatility of the technique. Chapter 9 takes this a step further by again adapting the methodology which, has historically been used primarily for infectious diseases, to consider reproduction and assess risks to welfare rather than purely health. The paper in Chapter 9 builds on the methodology by combining existing peer-reviewed literature with data collected specifically for the purpose of feeding into the assessment and utilising a stakeholder and expert opinion elicitation workshop to obtain data too. These process are proposed and described in Chapter 3.

The final chapter critically reviews risk assessment, highlighting three key areas of potential weakness and proposing approaches to address these criticisms. The value of the approach in wildlife and zoological health and welfare as demonstrated by this series of papers is described.

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Contents

Chapter 1: The Use of Qualitative Risk Analysis Methods to Facilitate Decision Making in the Management of Health and Welfare in Wildlife

1.1 Introduction

Risk analysis has been developed to provide an objective, repeatable, transparent and documented assessment of the risks posed by a course of action or chain of decisions (MacDiarmid, 1997), and can be constructed to include social, political, financial and practical factors influencing decision making (Rowe, 1980). Risk analysis is particularly useful as qualitative, rather than quantitative, approaches can be used so it can still be effective when numerical or statistical data are not available or data sets are small (Murray, 2004; Peeler et al., 2007). Different sources of evidence can be collected to feed into risk analysis; these include empirical data, peer-reviewed literature, grey literature and expert opinion (North, 1995).

The status of risk analysis as a science has often been questioned (Aven, 2012; Clark, Carrington & Bolger, 1998), as risk analysis does not generate accurate estimations and predictions (Cumming, 1981; Weinberg, 1981) and there is a lack of well-defined and universally-accepted series of terms and defined approaches (Aven, 2012). There are several critical reviews of risk analysis techniques, but these reviews, like the majority of the literature on risk analysis, are primarily focused on quantitative methods (Aven, 2011, 2012; MacDiarmid & Pharo, 2003; North, 1995; Renn, 1998) and the validity of mathematical formulae and models.

Risk analysis processes have been developed and used successfully in multiple human-centred disciplines, ranging from management of health and safety in the workplace (Pinto, Nunes, & Ribeiro, 2011) to food preparation hygiene (Michaels et al., 2004). Standardised risk analysis techniques have been developed that are used routinely to guide human and animal health policy making and disease control by governments and international organisations, such as the World Health Organisation (WHO) and World Organisation for Animal Health (OIE) (MacDiarmid & Pharo, 2003).

In this thesis of published works I focus on the use of risk analysis as a tool for evidence based policy and decision making in the management of free-ranging wildlife and zoo-managed animals.

1.2 The Risk Analysis Process

The initial stage in any risk analysis is to define the risk question (e.g. see Chapters 3, 5 ,8 and 9), to describe the background and context of the scenario. The risk question needs to clearly establish the goals, scope and focus of the analysis (Jakob-Hoff et al., 2014). These may be influenced by cultural and political history, stakeholder attitudes and positions, policy or regulatory limitations, resources and the decisions that need to be made. Assumptions and limitations should be recorded in order to promote transparency (Jakob-Hoff et al., 2014). Once the risk question has been defined, risk analysis is composed of four components: i) hazard identification, ii) risk assessment (with three stages see section 1.2.2), iii) risk management and iv) risk communication. This is shown in Figure 1 and discussed here.

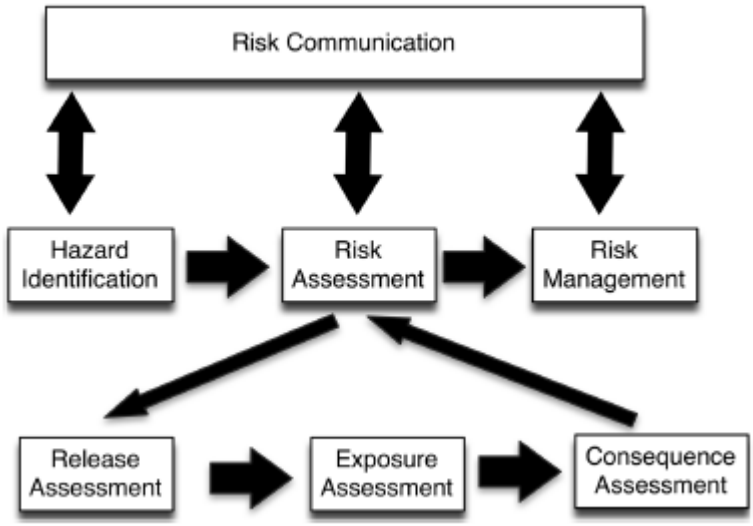

Figure 1: Diagram showing the process of risk analysis, highlighting the three-stage reiterative risk assessment process and the risk communication process that occur throughout the analysis.

1.2.1 Hazard Identification

A hazard can be defined as a biological, chemical or physical agent in, or a condition of, an animal or an animal product, with the potential to cause an adverse effect on health (Jakob-Hoff et al., 2014). Defining a hazard will require expert knowledge of the

susceptibility, epidemiology, distribution and properties of the hazards (MacDiarmid & Pharo, 2003).

1.2.2 Risk Assessment

The risk assessment is composed of a) the release assessment (the biological pathways for the introduction of the hazard), b) the exposure pathway (the biological processes that would result in the target being exposed to the hazard) and c) the consequence assessment (identification of the adverse effects on human or other animal health, the economy or environment). These three pathways are then modified by any risk mitigation measures, such as existing disease control policies or preventative disease measures, which are in place at the time of assessment before a risk estimation is undertaken. Risk estimation is essentially subjective based on interpretation of the significance of risk and levels of acceptable risk (Hathaway, 1991). This may include a combination of risk comparison methods with known historical data, cost-effectiveness assessment and cost-benefit analysis (Rowe, 1980).

The risk assessment can be developed using a wide range of additional tools, ranging from simple diagrams and spreadsheets to more clearly present the data, to bespoke software that develops quantitative assessments using data collected, to complex models exploring variability and uncertainty. A comprehensive review of available risk assessment tools is presented by Jakob-Hoff et al, (2014). The use of these tools does not divert from the risk analysis framework, but merely contributes to enabling risk conclusions to be reached and justified. Two commonly used tools are scenario trees and risk tables. Scenario trees are graphical models that identify the stages in the risk pathway (release, exposure, consequence) and can show confounding risk factors involved in driving the risk pathway. A risk table shows the steps in the risk pathway, summarises evidence, states the release, exposure and consequence assessment and produces a final risk estimation for the hazard or pathway (Hartley, 2010; Hartley et al, 2012; Jakob-Hoff et al, 2014). The risk assessment can be modified or repeated numerous times as new data and information become available, allowing risk management and risk communication to be modified appropriately.

1.2.3 Risk Management

Risk management is the process by which the risk manager (the person who is using the risk assessment to make decisions on the scenario) uses the results of the risk assessment, balanced with the 'level of acceptable risk' to determine the risk mitigation measures to be put into place (Hathaway, 1991). The levels of acceptable risk (and therefore the extent of the mitigation measures) will vary depending on financial and physical resources, ethics, public acceptance and other confounding factors.

1.2.4 Risk Communication

Risk communication is the exchange of information between risk managers, risk assessors and stakeholders throughout the risk analysis process (Jakob-Hoff et al., 2014; MacDiarmid & Pharo, 2003). This engagement maximises the quality of the analysis by ensuring it is relevant and realistic for decision-making and risk management (Westley & Vredenburg, 1997). Risk communication must be directed at technical experts, stakeholders and decision makers in order to gain information and insights to feed the risk assessment (MacDiarmid & Pharo, 2003). However, risk assessors must remain objective, separating technical risks from ethics, societal pressures and risk perceptions whilst integrating these influences into the assessment (Hathaway, 1991).

1.3 Development of Risk Analysis

Development of these procedures began in the 1930s and was advanced in the 1960's when a standardised format for quantitative risk assessment was published (Starr, 1969). The United States National Academy of Science (NAS) and National Research Council developed a uniform risk assessment model for use of all federal regulatory agencies in 1983 (Eduljee, 2000). This was designed to characterise the potential adverse health effects of human exposures to environmental hazards (Harvey, Mahaffey, Velazquez, & Dourson, 1995). These were later adapted and applied to infectious disease in humans (Lowrance, 1980), leading to the adoption of risk assessment into public health policy.

Covello & Merkhofer (1993) unified and standardised approaches for risk assessment across different specialised fields. Their refined risk assessment process is more

adaptable to animal health scenarios. They achieved this by modifying the NAS model to separate hazard identification into a separate process prior to the risk assessment. They introduced a 'release assessment' step that describes dissemination from the source of the hazard and redefined 'consequence assessment', recognising that the previously used dose-response concept originating from the environmental contamination field was too narrow as disease may have much more general effects on a wider range of targets. The Corvello-Merkhofer approach to risk analysis more readily accommodates the combination of objective scientific evidence and expert judgement and is less reliant on quantitative data and numerical estimates accommodating qualitative assessment. (North, 1995). These modifications have led to the Corvello-Merkhofer model being adopted as the basis for processes used by the WHO, OIE and World Trade Organisation (WTO). It has been demonstrated to be a highly flexible and appropriate approach to investigating disease risk in animals (Peeler et al., 2007).

The OIE Risk Analysis Framework (Murray, 2004) was developed for assessing the risks associated with the movement of live animals and animal products across international borders. This has formed a robust and reliable basis for the development of the broader disease risk analysis systems presented in this thesis and by other organisations, such as the UK's Department of Environment, Food and Rural Affairs (refer to Hartley & Roberts, 2015; see Chapter 2; Roberts, Carbon, Hartley & Sabirovic , 2011; and the Biosecurity Authority, Ministry of Agriculture, New Zealand; see Pharo, 2002). The framework has been used effectively for a range of scenarios beyond import risk analysis, including domestic animal notifiable disease incursion (Gloster, Mellor, Manning, Webster, & Hort, 2007), and pest species incursion (Andersen, Adams, Hope, & Powell, 2004) demonstrating its versatility. The OIE Framework is used as the basis for the risk analyses contained in this thesis, further demonstrating its adaptability to an even broader range of decision making. In relation to specific wildlife management issues, Davidson and Nettles (1992), Leighton (2002), Armstrong et al. (2003) and Miller (2007) devised qualitative methods for assessing the risks of disease specifically associated with wildlife translocations. Armstrong et al. (2003) and Miller (2007) also devised quantitative methods, facilitating assessments when numerical data were not available, which is frequently the case in wildlife decision making (see Hartley & Sainsbury, 2017 – Chapter 3). In 2014 the International Union

for Conservation of Nature (IUCN) and OIE jointly published the 'Manual of Procedures for Wildlife Disease Risk Analysis', which describes the technical tools and processes for wildlife disease risk analysis (Jakob-Hoof et al, 2014). The same organisations published the 'Guidelines for Wildlife Disease Risk Analysis' as a companion volume for decision makers to assist in the adoption of risk analysis as a tool (World Organisation for Animal Health (OIE) & International Union for the Conservation of Nature (IUCN) 2014). The work contained in my thesis directly contributed to the latter publication as I was one of four authors of this document. These two manuals collate and consolidate current knowledge and provide a framework for developing, interpreting and using disease risk analysis in wildlife conservation and are now used to set an acceptable standard for work in this field.

1.4 Why Use Risk Analysis for Decision-Making in Wildlife Health and Welfare?

Wildlife populations can have a significant influence on the epidemiology of exotic, endemic, zoonotic, new and emerging diseases (Daszak, Cunningham, & Hyatt, 2001; Sainsbury, Kirkwood, Bennett, & Cunningham, 2001), and these diseases may pose a risk to public health (Bengis et al., 2004; Chomel & Osburn, 2006). For example, the outbreak of Ebola virus in West Africa between 2013-2106 caused the deaths of approximately 11,000 people and the reservoir of this virus is thought to be bat species (Biek, Walsh, Leroy, & Real, 2006). Disease can transmit between wildlife and livestock (Artois, Delahay, Guberti, & Cheeseman, 2001; Clifford et al., 2009; Morgan et al., 2006). In the United Kingdom, badgers are integral to the epidemiology of tuberculosis (*Mycobacterium bovis)* in cattle (Delahay, Cheeseman, & Clifton-Hadley, 2001), which results in loss of productivity and culling of infected cattle. Consequently, in 2013 the UK government spent £99 million attempting to control this disease (Department of Environment, Food and Rural Affairs, 2014). Wildlife disease can also have a role in endangerment and extinction of species (Lafferty & Gerber, 2002; Smith, Sax, & Lafferty, 2006), such as avian pox, leading to significant declines in the endemic birds of Hawaii (van Riper III, van Riper, Hansen, & Hackett, 2002) and the fungal pathogen *Batrachochytrim dendrobatididis* has caused the extinction of several amphibian species (Skerratt et al., 2011).

New and emerging diseases are defined as diseases that have recently increased in incidence or geographical range, moved into new host populations, recently been discovered or caused by newly-evolved pathogens (Daszak et al., 2001; Daszak, Cunningham, & Hyatt, 2000; Epstein, 1995). The epidemiology of a considerable number of these pathogens or potential pathogens include wildlife species (Jones et al., 2008; Taylor, Latham, & Mark, 2001). For example, Nipah virus transmitted from fruit bat (scientific name) reservoir hosts can cause fatal febrile encephalitis in humans (Chua et al., 2000; Haydon, Cleaveland, Taylor, & Laurenson, 2002).

Pressures from habitat loss, human-wildlife conflict, non-native species and other extrinsic factors will continue to increase health risks to humans, livestock and wildlife (Daszak et al., 2001; Daszak et al., 2000; Jones et al., 2008; Polley, 2005; Tompkins, Carver, Jones, Krkošek, & Skerratt, 2015; Williams, Yuill, Artois, Fischer, & Haigh, 2002). Similar factors will continue to make managed zoo conservation programmes more integral to conservation (Conde, Flesness, Colchero, Jones, & Scheuerlein, 2011a, 2011b; Deem, Karesh, & Weisman, 2001; Hutchins & Conway, 1995).

The ability to make effective and accurate evidence-based decisions is imperative, so that interventions to prevent, limit the impacts, control or eradicate wildlife health threats can be taken (Artois et al., 2001; Ryser-Degiorgis, 2013; Sutherland, 2003). To make these complex decisions, which often involve multiple interventions, it will be necessary to consider several different courses of action. This requires the collation, review and interpretation of multiple sources of evidence, and risk analysis is one tool that can be used to do this. The technique is valuable because it can be used purely for risk assessment - the statistical calculation of probability of a consequence - or be expanded into other aspects of risk analysis, to include risk management and risk communication. This allows integration of social, ethical, cultural, communicational, financial and resource risk, which are all likely to influence a final decision.

Risk analysis is an iterative process. As the analysis is built, it may be recognised that some potential hazards have been missed or one of the risk pathways is not as first thought, and it is possible to modify the analysis to represent the best current knowledge. This modification may occur throughout the life of a project, as new

information from the literature or the project itself becomes available (Sainsbury, Armstrong, & Ewen, 2012). This adaptive management approach allows the process to respond to the dynamic ecology of the populations that are worked with, and continually improves the performance and accuracy of the risk analysis. For example, health surveillance data from post-release monitoring of reintroduced wildlife provides additional data for inclusion in an updated risk analyses for subsequent releases (Hartley & Sainsbury, 2017). Consequently, it addresses some of the evidence gaps and uncertainties faced.

1.5 Evidence as the Foundation of Risk Analysis

Some authors have criticised the range and sources of evidence used in risk analyses, and the fact that some of the information is based on assumptions, projections and judgements beyond the bounds of the data (Samet, Schnatter, & Gibb, 1998). This is particularly relevant in the fields of wildlife and zoo animal health and welfare, partly because it is only relatively recently that wildlife and zoological medicine has developed as a veterinary specialty (Aguirre, 2009; Stoskopf, 2006). Wildlife and zoological medicine integrates veterinary medicine, ecology and conservation science in both in-situ (in the wild) and ex-situ (outside the animals' natural environment) settings (Stoskopf, Paul-Murphy, Kennedy-Stoskopf, & Kaufman, 2001). Lack of funding for wildlife research and veterinary investigation is limited. In contrast, the commercial interests of maintaining domestic species in a productive state has enabled the funding of controlled studies that have provided empirical data, and therefore we have many hundreds of years of experience of housing a handful of specifically-bred domesticated species that have been subjected to intensive scientific research (Aguirre, 2009). In many situations, the data from domestic species provides a useful baseline to extrapolate to wildlife, but this is not always appropriate or accurate. For example, some species of antelope are not susceptible to some strains of Blue Tongue Virus, which cause clinical disease in domestic livestock (Sanderson, Garn & Kaandorp, 2008), and so comparisons between wild and domesticated species is not always useful.

The novelty of many diseases affecting wildlife, and the historical bias of veterinary knowledge to the domestic animal species, leads to considerable knowledge gaps in our understanding (Ryser-Degiorgis, 2013). For many diseases, species' susceptibility to pathogens is not known, the distinction between infection and disease has not been made and methods of transmission have not been identified (Gilmour & Munro, 1991; Gortázar, Ferroglio, Höfle, Frölich, & Vicente, 2007; Rhyan & Spraker, 2010). Diagnostic tests have not been developed and validated, and so if results are obtained they cannot be interpreted (Stallknecht, 2007). Population data needed for epidemiological studies include population size, density, age and sex structure, fecundity, home range size, habitat use and inter-species interactions, but are often not available for wildlife (Aiello et al., 2014; Stallknecht, 2007).

1.5.1 Approaches to Sourcing Evidence for Risk Analysis

There are three principal approaches to collecting evidence for risk analysis, namely surveying or interviewing experts or stakeholders; analysis of pre-existing data collected for a different purpose; and collecting data directly through purpose designed research (Carlstead, Mench, Meehan, & Brown, 2013). Undertaking specific supporting studies or collecting novel data to support development of a risk analysis is often not possible due to financial, technical and logistical constraints (Miller, 2007). In-fact, the lack of resources or time is often a reason why risk analysis is chosen as a tool for decision making. Instead of requiring novel data, risk analysis more commonly uses peer-reviewed literature and grey literature of relevance to the risk question. As these are obtained from studies conducted for other purposes they need very little or no specific funding.

Laboratory-based experimental infection studies in wildlife are associated with a range of challenges. These include animal acquisition, accommodation, artificial infection route, as well as recognised and unrecognised variables, such as genetics and exposure history. Alongside this, there are significant ethical and public acceptance concerns regarding experimental infection studies with infectious agents, such as Lyssaviruses and Simian Immunodeficiency Virus. In addition, important ecological and environmental factors could not be recreated experimentally and so research would not reflect the field situation (Ryser-Degiorgis, 2013; Stallknecht, 2007). For example, an experimental infection of *Mycoplasma conjuctivae* identified as causing

severe disease in wild Alpine ibex (*Capra ibex*) only caused a mild clinical signs in a captive herd (Giacometti et al., 1998). However, experimental infection studies can provide important baseline information for risk assessment. During the outbreaks of bluetongue virus in Europe in 2009-2011, experimental infection studies were undertaken in red deer *(Cervus elephas)*. These allowed risk-based decision making to be made regarding disease control and monitoring priorities, based on species-specific epidemiological information (López-Olvera, et al, 2010). Likewise, experimental infection studies in serotine bats *(Eptesicus serotine)* were undertaken with European Bat Lyssavirus to study virus incubation and transmission rates and inform public health protection actions (Freuling et al, 2009).

Field-based epidemiological and ecological research is reported widely in the peer-reviewed literature. These papers provide information on drivers, confounding factors and frequency of the occurrence of the hazard under investigation and therefore contribute to the release, exposure or consequence assessments of the risk analysis. Of particular interest to wildlife disease risk assessors are disease control intervention studies, which examine the effectiveness of potential control methods on the incidence of disease (Haydon et al, 2002). One of the largest wildlife intervention studies undertaken was the randomised badger culling trial (Donnelly et al, 2007), which was designed to inform tuberculosis control policy in the UK and was used as evidence for risk assessment (Delahay et al, 2007) in an attempt to better characterise transmission routes and improve disease control.

The scarcity of reported clinical cases of disease in wildlife, and the rarity of the focal wildlife species, results in a significant field effort to generate very small sample sizes and the frequent publication of single case studies. For example, although it is thought that Human Immunodeficiency Virus 1 originated in chimpanzees *(Pan troglodytes)*, only four individuals have been found to be naturally-infected with the source virus (Gao et al, 1999). Likewise, efforts to conserve and study the Critically Endangered saola (*Pseudoryx nghetinhensis*) have been impeded by the fact that the animal has rarely been observed since being discovered in 1992 (Kemp, Dilger, Burgess, & Van Dung, 1997). The significant cost and effort to undertake studies, and the poor yield of definitive results, hinders efforts to collect robust evidence for decision making.

A lack of historical data, lack of consistency in collection methods and difficulties in interpretation due to lack of standard systematic recording, results in few longitudinal data sets for zoo and wildlife species. This deficit makes the identification of disease emergence, change and spread challenging (Harvell et al., 2002). Many wildlife disease and ecological studies are limited to relatively short periods of study, driven by funding availability. Disease surveillance data and wildlife population monitoring data are collected, but the findings are often not reported in peer-reviewed sources. These are extremely valuable sources of long-term data for wildlife risk assessment, providing information on disease occurrence, prevalence and trends over time, allowing population level assessments to be made. Examples include the UK Wildlife Disease Surveillance Partnership reports (http://apha.defra.gov.uk/vet-gateway/surveillance/seg/wildlife.htm) and the Garden Bird Watch https://www.bto.org/volunteer-surveys/gbw, which has monitored and recorded garden bird populations for twenty-three years.

1.5.2 Expert Advice and Stakeholder Opinions

Where there are limited resources to collect new empirical data, or there is an urgent need to make decisions the elicitation of expert advice is a key method to address evidence gaps in complex systems (Kuhnert, Martin, & Griffiths, 2010; Martin et al., 2012). In some situations, there may be no empirical data available at all and expert opinion is the only or most credible source of information (Martin et al., 2012; Wilson, 2017), but there are still concerns that expert opinions can be biased, poorly calibrated or self-serving (Burgman, 2001; Martin et al., 2012).

However, there is a broad field of literature describing robust and efficient extraction and combination of opinions from experts (O'Hagan et al., 2006). If experts are being asked to use their knowledge to predict what may happen in a particular context, these are referred to as ‘expert judgements’ (Wilson, 2017). Expert opinion or judgements can be used at several different points in the qualitative risk analysis process. Input may be obtained during development of the hazard identification and risk pathway stages (Runge, Converse, & Lyons, 2011). Experts may review the risk analysis after it has been constructed and be used as a challenge function prior to entering the risk management stages of the process (Fletcher, 2005; Jakob-Hoff et al., 2014; Krueger, Page, Hubacek, Smith, & Hiscock, 2012) Opinions may also be sought during

development of the risk management and communication components where different information will be required. The decision of if, when and how to use expert opinion will depend on the nature of the information required and if these variables are impacting at the risk assessment or risk management stages of the risk assessment. Parameters where a lack of empirical knowledge is impeding the analysis should be prioritised (Martin et al., 2012). It should be predetermined what information is required, how it will be fed into the risk analysis process and how the opinions will be elicited (Burgman, 2001; Krueger et al., 2012). This will indicate whose opinion or judgement is needed and the area and level of expertise required, and will enable the recruitment of relevant people to the task.

The definition of an expert is controversial and is discussed in several studies (Burgman, 2001; Burgman et al., 2011; Krueger et al., 2012). An expert has knowledge on a particular topic not widely known by others and should be deferred to in the interpretation and application of this knowledge (Martin et al., 2012). Expert knowledge may be the result of training, research and skills, but also the result of personal experience (Burgman, 2001; Burgman et al., 2011). For wildlife health and welfare risk analysis purposes, a broad range of expertise may be required to contribute to the understanding of a single hazard or scenario. This multidisciplinary approach can involve epidemiologists, ecologists, diagnostic scientists, microbiologists, conservation scientists, population biologists, ethologists, animal managers and veterinarians, among experts from other fields.

It has been stated that in order to ensure the risk analysis process is not influenced by personal or public pressures, those contributing their opinion should not be decision-makers or be impacted personally by the outcome of the assessment (i.e. should not be stakeholders) (Burgman, 2001; Leighton, 2002). This might be possible when formulating the risk assessment component, but, when developing the risk management and risk communication approaches in the analysis, decision-makers and stakeholders will contribute important evidence in relation to likelihood feasibility and acceptability of courses of action (Fletcher, 2005; Hanisch-Kirkbride, Riley, & Gore, 2013; Krueger et al., 2012). For example, stakeholders may be the only source of information on local conditions, management practices and impacts (Krueger et al., 2012), and so the process would be hindered without their input.

The utility of the expert knowledge depends on the scientific rigour with which it is acquired and its accuracy (Martin et al., 2012). Knowledge may be given directly as statistical summaries or probabilities (Kuhnert et al., 2010) to feed directly into the analysis or, more commonly in wildlife and zoo animal scenarios, indirectly by asking the experts questions that relate to their experience, which the analyst then interprets (Martin et al., 2012). Many different techniques can be used to elicit expert knowledge, including telephone interviews, questionnaires and individual interviews (Burgman, 2001). However, many risk assessors recommend that a well-prepared workshop should be organised, in which an appropriate range of experts, stakeholders and decision-makers are gathered for a facilitated, structured review and analysis of the scenario (Fletcher, 2005; Jakob-Hoff et al., 2014). In these group meetings, it should be considered if the multiple experts give evidence individually to ensure independent, uninfluenced representation or if group discussion allowing concensus opinion should be sought. This will depend on the risk question and the desired outcome of the analysis. If the analysis is required to aid the choice of a preferred option the former may be most useful, whereas if the analysis is considering the risks associated with the impacts of a course of action already chosen a broad consensus may be more useful. Workshops must be facilitated, preferably by an independent person, so that the evidence is not biased by dominance of certain individuals and loss of diversity of opinions, but so that clear, coherent and representative conclusions are reached (Jakon-Hoff et al, 2014).

The use of expert opinion can generate uncertainty where there is expert disagreement. In such cases, it is necessary to explore the implication of the judgements to determine their impact on the final conclusions. Experts may disagree on the body of knowledge or draw different inferences from an agreed body of knowledge. There are two key approaches to combine a diversity of opinions, the first being behavioural aggregation, which involves generating a consensus opinion (Burgman, 2001; Wilson, 2017) using either opinion pooling or Bayesian data analysis techniques (Burgman, 2001; Wilson, 2017). The use of models has the advantage that experts are not required to pinpoint a single probability measure and that imprecision can be reflected in the outcome using probability (Troffaes, 2003). The second method to combine diverse opinions is the Delphi technique and its many variants

(Runge et al., 2011; Wilson, 2017). The Delphi technique involves experts giving individual anonymous estimates to set questions, which are then discussed in a forum and modified in light of the others responses (Powell, 2003). The Delphi technique has the advantages that it is quick, cheap encourages sharing of knowledge, allows equal expression of opinion and generates concensus. Disadvantages are that the process allows a lack of accountability, the outcome can be heavily influenced by participant selection and that watered-down conclusions reflecting the lowest common denominator are reached (Powell, 2003).

1.6 Quantitative or Qualitative Risk Assessment?

There are two broad approaches to risk assessment. A qualitative risk assessment uses subjective categories (e.g. low, medium, high), conversely, quantitative assessments use numerical data to quantify parameters and their uncertainty, such as rates, probabilities and frequencies and are regarded as being more objective. Risk assessments may also be an amalgamation of the two approaches, and in such cases these are called semi-quantitative.

The challenges of attempting quantitative risk assessment with poor data have been recognised. Models based on incomplete or inappropriate data cannot be validated and rely instead on mathematical assumptions, rather than a knowledge of biology, and therefore result in a wide variation in risk estimates (Carter, 1991). Additional concerns have been raised about the ability for quantitative and statistical risk assessment to account for interacting uncertainties and inter-dependencies, presenting the scenario as too simplistic and giving an illusion of precision (Hardman & Ayton, 1997). For example, Bayesian analyses that are often used in quantitative risk analysis, traditionally require mutual exclusivity of hypotheses, whereas in real systems this is rarely the case because biological systems are complex and influenced by many factors simultaneously. (Hardman & Ayton, 1997). Hood and Jones (2003) argue that quantitative methodologies were originallly developed under the assumption of closed systems, which consider objective risks with a finite number of outcomes and therefore lend themselves to precise measurement. If used for more

subjective, open system risks, such as biological scenarios with an unlimited or unpredictable number of options, they will be unreliable.

Comparative risk assessments using quantitative techniques are particularly difficult, as they require that all the release and exposure pathways are quantified for each scenario (Jackson et al, 2009). For example, when assessing the risk of disease incursion through imports of wildlife bushmeat, no data are available for illegal imports; in such situations, qualitative approaches may be more appropriate when assessing relative risks. In contrast, quantitative techniques are far superior for assessing changing risks, for example after the introduction of a new intervention. Post-modification data can be fed into the same risk assessment, producing a directly comparable measure of risk. In contrast, changes in risk may potentially be missed when consumed into the very broad subjective bands of qualitative assessments, which would limit their use.

Qualitative approaches are useful for rapid assessments when little or no quantitative data exists (Jackson et al, 2009). In these situations where numerical data is scarce or unreliable, risk assessment techniques must be modified to provide a framework that conveys meaningful risk information so that a decision can be made (Krause et al., 1995). Semi-quantitative risk assessments use data that are available, in combination with more subjective information. For example, Delahay et al. (2007) used the results of post-mortem examinations to calculate the prevalence of tuberculosis infections in wild mammals and used scored, weighted expert judgements to generate excretion and contact rates to produce a risk estimate. This study generated novel evidence of the role of wildlife in tuberculosis epidemiology, indicating a previously uncharacterised risk.

Even when a qualitative risk rating is used to express outcomes, scoring systems and rankings can be introduced to identify uncertainty and data shortfalls (Jackson et al, 2009). Weightings may be used to signify magnitudes of impacts. These systems can be used to provide a numerical risk score to components of the data to introduce mathematical models and calculations. Baker et al. (2008) designed a qualitative risk assessment process for the introduction of non-native species into the U.K. This system included weightings of the magnitude of the potential consequences and

numerical scores for likelihood of entry and its establishment. This allowed direct comparisons to be made between different non-native species to aid with interpretation and prioritisation.

Expert opinion can be used to provide judgments for quantitative analysis, where they are asked to state a specific probability. In some circumstances, however, experts provide numerical probabilities demonstrating such significant levels of uncertainty that it undermines the assessment. This occurred during the Bovine Spongiform Encephalopathy crisis in 1996 where risk probabilities were so great that the public credibility of risk analyses was destroyed and risks of cross-species transmission rejected that in fact were correct (Beck, Asenova, & Dickson, 2005).

For qualitative risk assessments, information from experts and stakeholders can be collected in an unstructured manner, which, in some circumstances where broad holistic input is required, may generate the most useful contributions. However, a more systematic method involves asking experts a series of questions, which may all be equally important or may be ranked and scored. One or more expert is asked to answer each question with a categorical response. The results can then be analysed using mathematical approaches to produce a semi-quantitative assessment (Jackson et al, 2009). Additional numerical data can be generated by estimating the level of uncertainty in each experts' answer and their level of expertise in each question, which provides indication of uncertainty.

It has been recommended that all risk analyses should first be attempted qualitatively (Vose, 2001). Expending further resources on a quantitative assessment depends, firstly, on whether the qualitative results were adequate and appropriate for decision-making and secondly, on whether resources, expertise and data are available for a quantitative analysis (Peeler et al, 2007).

1.7 Dealing with Uncertainty

Historically the view was taken that if there is insufficient information the risk assessment process should be halted (Leighton, 2002). However, as seen in the field

of wildlife and zoo health, such an approach is not realistic as invariably there are large gaps in data, meaning that few assessments could be completed (Regan et al., 2005). It is important to acknowledge data limitations and uncertainties, but a lack of reliable data should not be a limitation of producing a risk assessment (Wooldridge, 2000). Risk assessment is often used because there is a lack of specific empirical data, so there is often a choice between a highly uncertain answer produced by risk assessment or no answer at all (Clark, Carrington & Bolger, 1998; Fletcher, 2005).

It is important to state clearly the areas and extent of the uncertainty. This is almost as important as giving estimates of risk, particularly in the early stages of assessment when uncertainties may be large and the data poor (Clark, Carrington & Bolger, 1998). The risk assessment can highlight specific data inadequacies and deficiencies and allow sensible targeting of resources to collect essential data to improve it. Although uncertainty is integral to risk assessment, it often remains neglected or at best unreported, because calculation of uncertainty can be complicated and difficult. A high level of uncertainty in a risk assessment raises questions about its validity and because high uncertainty makes the risk manager's job much more difficult (Clark, Carrington & Bolger, 1998).

Uncertainty can be classified in many ways and is reviewed comprehensively by Briggs, Sabel, & Lee (2009) and Regan, Colyvan, & Burgman (2002). Epistemic uncertainty occurs when there is a lack of precise knowledge due to insufficient data, extrapolation and variability (Briggs et al., 2009; Burgman, 2001; Martin et al., 2012; Regan et al., 2002). In theory, this can be reduced further by research and investigation (Regan et al., 2002; Runge et al., 2011). Aleatory uncertainty is caused by natural variation, which can be better understood, but not reduced, by collecting additional data (Martin et al, 2012). Linguistic uncertainty arises because language and vocabulary is not exact and therefore differences in interpretation or effectiveness of communication arise (Briggs et al., 2009; Burgman, 2001; Martin et al., 2012; Regan et al., 2002). This can be reduced by carefully defining terms, concepts and approaches (Burgman, 2001; Regan et al., 2002). Wildlife and zoo animal health and welfare risk analysis will be affected by all of these uncertainties.

It must be understood that there are elements of uncertainty in all forms of evidence that can potentially contribute to a risk analysis. Extrapolation of evidence regarding a different hazard or confounding factor assumes that the data are applicable to the risk under investigation when it may actually be incomparable. Experimental studies may not reflect the situation in the field. Longitudinal datasets may suffer from methodological drift over periods of time and published scientific studies may be flawed. Expert opinion and judgements can suffer from bias, ignorance or over confidence, and it is important to recognise that absence of evidence does not signify evidence of absence.

In the literature, it is stated that uncertainty should be presented in a quantitative form using probability distributions (Briggs et al., 2009; Clark, Carrington & Bolger, 1998) and there are many papers that describe this is achieved (e.g. see Briggs et al., 2009). However, there are few descriptions of how to present uncertainty when available data, or the risk question being considered, do not allow calculation of probability and therefore there is no consistent way of expressing uncertainty in qualitative risk analyses.

Likert-type scales, ranking of sources of uncertainty relative to each other or diagrammatic representation of uncertainty, can be used to present qualitative information (Briggs et al., 2009). Narrative explanations for the reasons for uncertainty at each stage in the risk pathway have been advocated (Briggs et al., 2009; Fletcher, 2005). Retaining differences in opinions and judgments, and presenting these as uncertainty, is important to communicate to risk managers (Burgman, 2001; Fletcher, 2005; Martin et al., 2012; Runge et al., 2011). This is because an uncertainty statement provides evidence that the risk assessment represents an account of what is known now (Clark, Carrington & Bolger, 1998). These methods aid transparency and enable risk managers to make separate decisions on different components of the problem where the level of acceptable risks may be different.

1.8 Developing Risk Analysis for Use in Wildlife Health and Welfare

In wildlife and zoo animals, the lack of population level studies, lack of a formulaic approach to animal care and access to only small numbers of limited species (many

thousands of species are not held in captivity) severely restricts the use of standard experimental approach to collecting evidence and making decisions (Pullin, Knight, Stone, & Charman, 2004; Sutherland, Pullin, Dolman, & Knight, 2004). Severely limited funding for wildlife and zoo health studies makes addressing these knowledge gaps difficult (Rhyan & Spraker, 2010). There are numerous health and welfare scenarios where evidence-based decision making is required, but is compromised by lack of evidence, lack of resources or a need for urgency, for example, management of pangolins in captivity (Hua et al., 2015; Yang et al., 2007) and the role of wildlife in the epidemiology of Ebola virus (Leroy et al., 2004; Rouquet et al., 2005).

Risk analysis has rarely been used to aid decision-making in wildlife and zoo health, but has significant potential to support formulation of evidence-based policies in these circumstances where there is an element of uncertainty, confusion or controversy (Hathaway, 1991; North, 1995).

Major steps forwards have been achieved in embedding risk assessment in the field of wildlife disease through the recent publication of IUCN guidelines for wildlife disease risk analysis (Jakob-Hoff et al, 2014). This publication confirms general recognition of the usefulness of risk assessment as a tool especially in a field where data is severely lacking and difficult and expensive to generate. Although the IUCN guidelines provide an important review and a description of the approaches and tools available to risk analysts, they do not provide a single standardised approach. However, this is not possible or desirable: the field of wildlife health and welfare is so diverse, and the problems being assessed are so varied, that the methods need to be adapted to enable us to address the specific needs of the risk question. The basic framework for risk analysis is established and described in section 1.3. Despite the need for modifications and adaptations to the process over time, zoo and wildlife health risk analysis should follow the basic scientific principles and approaches that have been developed, to ensure that the output is valid, transparent and accepted.

Very few animal health risk analyses have been published in peer-review literature (MacDiarmid, 2000) and even fewer wildlife and zoo health and welfare risk assessments have been published. This reliance on unpublished sources of information restricts sharing of good practice, experience and constructive challenge

therefore limiting development of new approaches which would develop risk analysis further (Jakob-Hoff et al, 2014) and encourage wider acceptance and adoption of the process for decision making. The work presented in this thesis makes a significant contribution to the published risk analysis literature. I have contributed to the development of best practice methods and approaches (Hartley & Sainsbury, 2017 – Chapter 3), integration into decision and policy making (Hartley & Lysons, 2011 – Chapter 6) and demonstrated broad practical application of the themes of these papers in several diverse fields presented here in Chapters 2, 4, 5, 7 and 8.

In this thesis, I investigate the use of risk analysis techniques in a range of scenarios requiring evidence-based decision-making in the field of wildlife health and welfare in both in-situ and ex-situ environments and consider how risk analysis is used as a tool during the decision making process. Five key hypotheses are posed to investigate the usefulness and robustness of risk analysis as a decision making tool for wildlife health and welfare. In Chapter 10 I critically discuss the field in the context of my work and identify future areas for development.

1.9 Hypotheses

1. Outputs from risk analyses can contribute to evidence-based decision making in wildlife health and welfare
2. Risk analysis techniques are flexible and can be adapted to a range of wildlife health and welfare scenarios
3. Risk analysis techniques can successfully use a range of evidence from different sources and of different quality, in order to address wildlife health and welfare. Issues
4. The use of both quantitative or qualitative risk assessment techniques are valid for effective decision making in wildlife health and welfare.
5. Risk analyses can be undertaken that reflect and communicate uncertainty around decision making in wildlife health and welfare.

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Chapter 2: Risk Analysis for Importation Policy Development. Disease risk analysis – A tool for policy making when evidence is lacking: Import of rabies-susceptible zoo mammals as a model.

2.1. Authorship statement

Dr Helen Roberts contributed to this paper by providing expertise on the import risks and policy decision regarding domestic animal rabies import policy and reviewing the paper prior to submission for publication. The development of the methodology and the analysis of the evidence regarding the wildlife species was my work.

2.2 Introduction to published paper

The published paper in this chapter (Hartley & Roberts, 2012) assesses the risks of the importation of rabies susceptible zoo animals into the United Kingdom. In this paper, traditional risk analysis methodologies have been developed by incorporating multiple species in a single assessment and addressing challenges caused by a significant lack of peer-reviewed evidence on which to base policy development. This is the first time the full evidence base for UK government import policy was published in a peer-reviewed journal.

Historically, a significant driver of the development of animal disease risk analysis was for assessing risks of the importation of live animals and animal commodities into individual countries (Metcalf, Blackwell, & Acree, 1996; Peeler et al., 2007) triggered by the introduction of the Sanitary and Phytosanitary measures by the World Trade Organisation in 1995. This agreement aimed to facilitate trade whilst allowing the protection of human, animal and plant life. The OIE Framework for Risk Assessment was developed as the science-based method to determine appropriate disease protection measures (Bruckner et al., 2010; Murray, 2004). The general approach to import risk assessment in the UK is described by Roberts, Carbon, Hartley & Sabirovic (2011). Import risk assessments for domestic animals may be quantitative or semi-quantitative depending on the availability of numerical data (Metcalf et al., 1996;

Peeler et al., 2007; Roberts, Carbon, Hartley, & Sabirovic, 2011). This risk assessment, in this publication, is stated in qualitative terms as the underlying evidence is not accurate or specific enough to allow for a quantitative calculation of risk to be made.

Risk assessments undertaken for trade purposes will focus on an individual commodity, and the hazard identification will consider all potential pathogens (Peeler et al., 2007; Torgerson & Craig, 2009). These are the most commonly undertaken and reported disease risk analyses, but the depth and scale of the data required to undertake a comprehensive assessment are still considerable (Kahn, 1999; Mur et al., 2012; Paton, Sinclair, & Rodriguez, 2010).

Import risk assessment may also be undertaken for determination of biosecurity policy or to assess the disease risks associated with policy formulation or change (Peeler, Thrush, Paisley, & Rodgers, 2006). In these scenarios, the starting point for the assessment is the specific pathogen, and the hazards are those animals or animal products that could be infected with the pathogen that crosses the geographical border.

Import risk assessments have been used in the field of wildlife and zoological animal health as discussed in Chapter 1. In these species, the limited data available are often of poor quality and so qualitative approaches have to be adopted. Much concern has been raised over the potential risks from importations of exotic pets (Carrete & Tella, 2008; Pavlin, 2009; Smith et al., 2009), bush-meat (Chaber, Allebone-Webb, Lignereux, Cunningham, & Rowcliffe, 2010; Falk et al., 2013) and wildlife for hunting (Martínez-López, Perez, & Sánchez-Vizcaíno, 2009), but due to the lack of import controls, few commodity-focused assessments have been undertaken to assess these risks systematically (Bomford, 2003; Bomford, Kraus, Braysher, Walter, & Brown, 2005).

Policy development risk assessments are less common but one example was produced by Peel, Hartley, & Cunningham, (2012) who studied the risk of importation of the amphibian pathogen *Batrachochytrium dendrobatidis.* The paper in this chapter (Hartley & Roberts, 2015) is a more complex risk assessment, as it includes multiple

taxa and species, that was undertaken in order to review the policy for the importation of rabies-susceptible zoo and exotic animals. This work was part of the evidence base for policy changes for the importation of rabies-susceptible species into the UK. This paper highlights the challenge of wildlife disease risk assessments, as it was commissioned, by the UK government to address gaps in species coverage left following completion of several quantitative risk assessments focused on domestic animals (Goddard et al., 2012; Jones, Kelly, Fooks, & Wooldridge, 2005; Weng, Wu, Yang, Tsai, & Chang, 2010). Rabies in domestic animals has been studied extensively and data are collected routinely. The authors in the studies cited above had experimental and case study evidence regarding incubation periods of rabies in dogs, cats and ferrets. This meant they could calculate the probability of infection rate using models based on the number of cases or rabies reported and the size of the animal populations. Vaccination efficiency and efficacy in domestic animals has been demonstrated and diagnostic test reliability is proven through vaccine license trials and test validation procedures. The number of companion animals entering the UK annually is collected as is data on the interception of illegally imported animals at border controls. In zoo mammals, empirical data on rabies susceptibility and incubation periods are known for only a small number of relevant species and furthermore none of the other data described above are available for zoo and wildlife animals. The paper presented in this chapter describes how the limited data are used to make a coherent and evidence-based policy recommendation for the import of zoo animals which is consistent with the approaches taken for domestic species.

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2.4 Published paper

Disease risk analysis - A tool for policy making when evidence is lacking: Import of rabies susceptible zoo mammals as a model.

Matt Hartley and Helen Roberts

Abstract

Disease control management relies on the development of policy supported by an evidence base. The evidence base for disease in zoo animals is often absent or incomplete. Resources for disease research in these species are limited and so in order to develop effective policies, novel approaches to extrapolating knowledge and dealing with uncertainty need to be developed. This paper demonstrates how qualitative risk analysis techniques can be used to aide decision-making in circumstances where there is a lack of specific evidence using the import of rabies susceptible zoo mammals into the United Kingdom as a model.

Introduction

Animal disease control policy is formulated using a range of scientific evidence sources such as peer-reviewed literature, veterinary research - both independent and government funded, and through disease surveillance systems (Davies, Tas, Gillam, 2010). Due to the large numbers of animals kept, and the wide variety of possible transmission routes, both to other animals and humans, the generation and assessment of evidence for policy making is primarily focused on food producing and to a lesser extent, pet animals. Indeed, specific research in excess of £35million was commissioned to address the evidence needs of UK veterinary policy in 2013 (Defra personal communication).

However, animal disease control policy also applies to zoo animals and can cause significant impact on welfare and the management of conservation breeding programmes. There is a lack of peer-reviewed literature and extremely limited disease research being undertaken regarding disease in non-domestic captive species. This creates evidence gaps when creating and refining disease control policy.

Risk assessment is a tool intended to provide decision makers with an objective, repeatable and documented assessment of the risks posed by a particular course of action (MacDiarmid, Pharo,1997). It is a tool now routinely used to guide policy making and disease control planning by governments and international organisations such as the OIE (World Organisation for Animal Health) and the International Union for Conservation of Nature (IUCN).

Since 1st January 2012 the UK has harmonised with the European Union on the rules governing the movement of pets (Fooks, Horton, Johnson, Toth, Roberts, 2011). Before this date, pets were imported under the Rabies Importation of Dogs, Cats and Other Mammals Order (1974) and its amendments. Mammals imported into the United Kingdom from countries that have not declared an official rabies free status under Article 8.10 of the OIE Terrestrial Animal Health Code were required to be housed for six-months in official rabies quarantine.

In the 40 years since the enacting of this legislation our understanding of the transmission, susceptibility and epidemiology of rabies has improved considerably and therefore the UK government considered the import legislation was out-dated, disproportionate and not supported by current evidence. The requirement to harmonise rules with Europe initiated a thorough policy review.

A comprehensive qualitative veterinary risk assessment, focused on the risk of the importation of rabies into the United Kingdom (Wilsmore, Hablin, Taylor, Taylor, Watson, 2006) had included domestic animals and wildlife but had not included the wide range of species that may be imported into the UK, as part of zoological breeding programmes. This study addresses this issue and collates evidence to support introduction of a risk-based policy regarding the importation of rabies-susceptible zoo mammals into the UK.

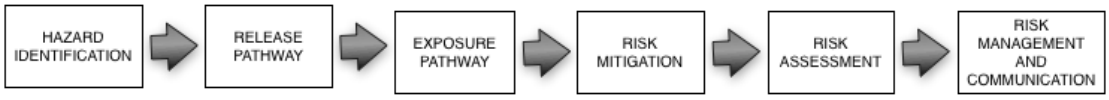
Materials and Methods

The methodology utilised was developed for the specific requirements of the policy-making process within the Department of Environment, Food and Rural Affairs. This process is closely aligned with the OIE Risk Assessment Framework (OIE,2007) for qualitative import risk assessment and has been endorsed through a process of peer review and publication (Roberts, Carbon, Hartley, Sabirovic, 2011).

The risk assessment is composed of 6 components as shown in Figure 1.

Figure 1

The six components of risk analysis as determined by the OIE.



The risk assessment uses the risk terminology as shown in Table 1.

Table 1

Risk terminology used in this study.

Term	Definition
Likelihood	Probability; the state or fact of being likely
Likely	Probable; such as well might happen or be true; to be reasonably expected
Negligible	So rare that it does not merit to be considered;
Very low	Very rare but cannot be excluded;
Low	Rare but does occur;
Medium	Occurs regularly;
High	Occurs very often.

The risk question was determined as: ‘The risk of introducing rabies virus to the UK through the movement of animals not covered by the new harmonised EU Pet

Movements Legislation but previously regulated by the Rabies Importation of Dogs, Cats and Other Mammals Order (1974).'

Hazard identification

In this risk assessment the hazard is classical rabies virus infecting an animal housed in a zoological collection in the UK.

Release and exposure pathways

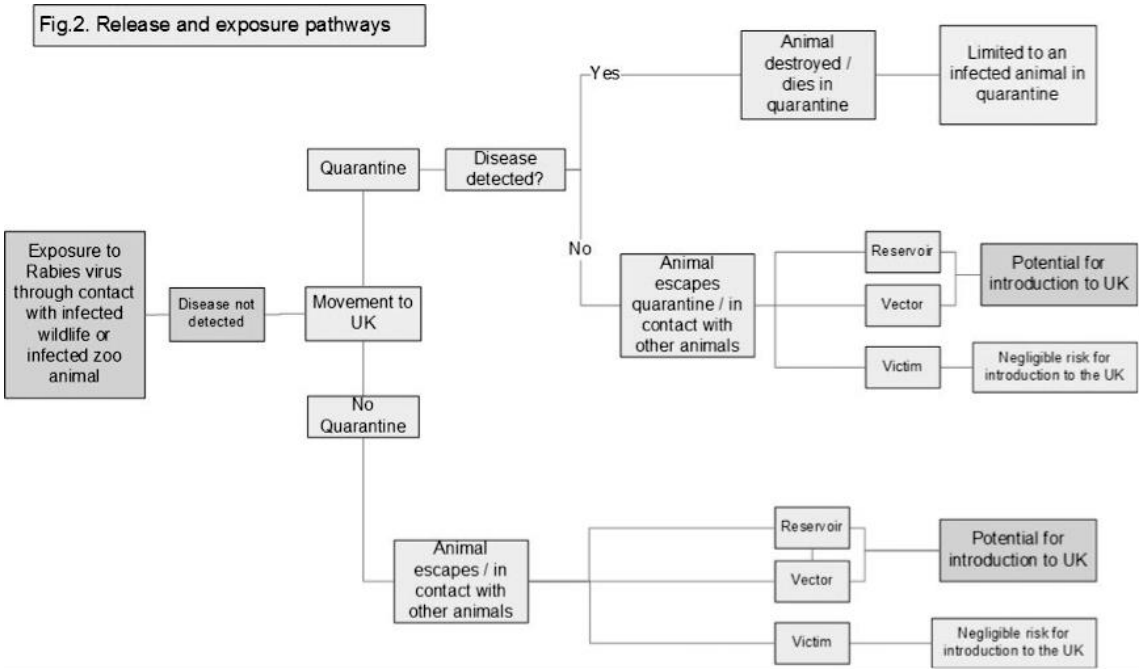


Figure 2
Release and Exposure pathways for the import of rabies susceptible zoo species into the UK.

Displaying the release and exposure pathways in a diagrammatic form aids interpretation and understanding of the often complex epidemiology of disease and simplifies the process into individual steps. Focused evidence can then be collated and reviewed for each step in the pathway.

The release pathway concerns the likelihood of the zoo animal being infected, whilst the exposure pathway concerns the likelihood of an infected animal transmitting rabies to other animals. The effect of quarantine on disease control is demonstrated, this is the risk mitigation process in this assessment.

The risk pathway has identified the key factors which determine the risk under the analysis namely; a) the likelihood that the animal is susceptible to rabies b) the likelihood of the animal transmitting the disease to others c) the incubation period of the virus in susceptible species as this contributes to the likelihood that infected animals are detected.

Results

Risk analysis

A full literature review of rabies infections in non-domestic animals was undertaken. This highlighted the lack of information available and the limitations of evidence for this review. There is only one report of classical rabies infection in a zoological collection (Enurah et al, 1988) therefore reports of rabies in free-ranging wildlife were used as the key evidence base.

Under the Rabies Importation of Dogs, Cats and Other Mammals Order (1974) there were three categories of animals each of which have different import requirements.

Schedule 1, Part 1 - *Desmodontidae* (Vampire Bats) are required to be detained and isolated in quarantine for the rest of their life, at the owners expense.

Schedule 1, Part 2 – *Carnivora, Chiroptera, Dermoptera, Edentata, Hyracoidea, Insectivora, Lagomorphia, Marsupilia, Primates* and *Rodentia* are required to be detained and isolated in quarantine for a period of six months at the owner's expense.

Schedule 1, Part 3 - *Artiodactyla, Monotrema, Perissodactyla, Pholidota, Proboscidea, Tubulidentata* are subject to provisions of the order and taken into custody of an inspector when they have come into contact with an animal, listed in Schedule 1 parts 1 and 2, which has escaped from quarantine, is housed on a vessel in port or is suspected of being illegally landed.

Monoclonal antibody and nucleic acid studies have shown that classical rabies virus infections in terrestrial mammals can be linked to distinct virus variants. Each variant is maintained primarily by intraspecific transmission within a dominant reservoir, which is responsible for maintenance and spread of the virus. Disease in other animals represents spill-over of infection resulting from sporadic contact with the major host species (Smith & Baer, 1988). Some of these spill-over hosts may act as effective vectors of the disease but not act as true reservoirs (Rupprecht, Hanlon, Hemachuda, 2002). The final category of terrestrial mammals are classed as 'victims'. These animals die of overt disease without the usual opportunity for onward transmission and therefore secondary case development (Rupprecht, et al, 2002). This is summarised in Table 2.

Table 2

Susceptibility of zoo mammal species (as defined in Rabies Import Order 1974) to infection with Lyssavirus 1 and their consequent classification.

Animals	Category	References
Vampire Bats *(Desmodontidae)*	1: Reservoir	[23]
Chiroptera (not Desomodontidae); Canids, Felids, Mustelids, Procyonids, Viverridae, Ursids, Hyanids	2: Reservoir or Vectors	[1, 2, 3, 4,10, 12, 14, 17, 19, 20, 26, 34, 36, 35,
Primates	3(a): Victim	[1, 11, 23, 29, 31, 34]
Dermoptera Xenartha, Hyracoidea, Eulipotyphyla, Marsupalia	3(b): Victim	[1, 31]
Lagomorpha	3(c): Victim	[5, 21, 24]
Rodentia	3(d): Victim	[1, 5, 8, 12, 21, 24, 39]
Pinnipeds	3(e): Victim	[26]

The vampire bats *(Desmodontidae)* represent the most important reservoir of classical rabies virus; they are infected for life, rarely show clinical signs and rarely die from infection (McColl, Sikes, Silberman, 2000).

There are numerous examples of the reservoir/vector/victim epidemiology in wildlife populations. A survey in Brazil found classical rabies commonly in bats and also reported spill over into primates, opossums and other wildlife (Almeida, Massad, Aguiar,Martorelli, Joppert, 2001).

Canids are the maintenance host species for several of the strains of rabies. Domestic dog rabies predominates in Central and South America, Asia and Africa. This strain is most commonly associated with human cases. This strain has 'spilled-over' into African Wild Dogs *(Lycaon pictus)* and domestic cattle (Gascoyne, Laurenson, Lelo, Borner, 1993)

An African fox strain circulates primarily in the bat-eared fox *(Otocyon megalotis)* but also the Cape fox *(Vulpes Chama)* (Swanepoel, Bernard, Meredith, Bishop, Bruckner et al, 1993) In Europe, rabies is associated with the red fox (*Vulpes vulpes)* strain and has spilled over to a variety of other species including Europe badgers *(Meles meles)* which are efficient vectors of fox strain rabies (Pastoret, & Brochier,1999). Artic fox *(Alopex lagopus)* specific variant circulates in wild animals in Alaska, Scandanavia and Russia. Spill over has occurred into polar bears, reindeer, wolves and a seal.(Ballard, Follmann, Ritter, Robards, Cronin, 2001; Odegaard & Krogsrud, 1981; Taylor, Elkin, Maier, Bradley, 1991).

Three distinct rabies strains circulate in skunks (*Mephitis mephitis*) in North America. Spill over cases have been recorded in otters *(Lutra canadensis*) and fishers *(Martes pennati*) both of which act as efficient vectors (Krebs, Strine, Smith, Noah, Rupprecht, Childs, 1995). Racoon rabies is the most common strain of rabies in the USA and is widespread. This strain has spilled over into a wide variety of wildlife (Kamakawa, Koiwai, Satomura, Eto, Sugiura, 2009; Torrence, Jenkins, Glickman, 1992). A specific mongoose adapted strain has been identified in Yellow Mongoose *(Cynicitic penicillata)* in South Africa and also possibly Slender Mongoose *(Galerella sanguinea)* in Zimbabwe. The closely related Meerkats *(Suricata suricata),* Water mongoose *(Atilax paludinosus)* have also been confirmed with this strain (Foggin, 1988; Swanepeol et al, 1993).

Felids are infected with the endemic circulating strains of rabies virus and can act as vectors but felid populations do not act as reservoirs for infection. Lions became infected in Namibia after preying on Kudu, which had been infected by Jackal. Lions, African wild cats and Caracal have been reported with rabies in an area with an outbreak of rabies in jackal (Berry,1993).

The variable susceptibility and the epidemiology of the disease means that species can be classified according to a particular status of reservoir, vector or victim, which determines the risk they pose of causing onward transmission when infected with rabies.

Fundamental to both the release and exposure pathways is the incubation period of rabies virus in zoo mammals. Unlike many etiological agents, a productive infection by a lyssavirus usually kills its host. Thus onward transmission usually only effectively occurs during the relatively short excretion period of the virus during the final stages of the disease. This very small window of infectivity is generally concomitant with illness or in the prior 3-10 days. Virus excretion several weeks before clinical signs is unusual. Bats differ from this, the period of infectivity is unknown but can be a much longer period of time. The vampire bats (*Desmondontidae)* are one of the most important reservoirs of rabies in humans and mortality in the bats is low (McColl et al, 2000). Therefore, there is a risk that vampire bats may be persistently infected.

The incubation period (time between initial infection and onset of clinical signs) determines the length of any recommended quarantine period. The quarantine period must be long enough therefore to also cover the infectious period. However there is limited additional information on the incubation period of rabies in non-domestic species summarised in Table 3 .

Table 3

Incubation periods of Rabies virus determined in non-domestic species.

Species	Incubation period (days)	Natural or Experimental Infection	Reference
Squirrel Monkey	18 -19	Experimental	[29]
Grey Wolf	16 - 21	Natural	[5]
Skunk	35	Experimental	[21]
Squirrel	18-86	Experimental	[39]
Kangaroo Rats	10-26	Experimental	[39]
Cactus Mice	15-34	Experimental	[39]
Laboratory Rats	12-71	Experimental	[39]
Cotton Rats	11-73	Experimental	[39]

The qualitative risk assessment of the introduction of Rabies into the United Kingdom concluded that 'scientific evidence with regard to rabies incubation periods indicates that there is very low risk associated with a reduction of the length of quarantine from six months to four months'.(Wilsmore, Hablin, Taylor, Taylor, Watson, 2006) Other risk assessment studies have supported this position.(Fooks, Horton, Johnson, Toth, Roberts, 2011; Jones, Kelly, Fooks, Woolridge, 2005; Kamakawa et al, 2009) . This risk assessment is related to the movement of pet dogs and cats and therefore should be treated with caution, but generally this will apply to most rabies-susceptible species. The table above showing known incubation periods in exotic animals does not provide any evidence to suggest that this is not appropriate for zoo animals.

The evidence collated in the risk analysis is used to assess the risks with no policy intervention. The risk mitigation process defines the potential control measures and reviews the risk assessment with these in place. In this way, the effects of the proposed policy can be demonstrated.

Risk mitigation and management

For each individual zoo mammal importation, a number of potential mitigating factors which will differ according to the animal's history must be considered in order to refine the import risk, these are :

1) The origin and destination of the animal, in particular the rabies status of the country of origin.
2) The disease surveillance, investigation and control standards of the premises of origin.
3) The time the animal has spent in premises of origin, if not since birth.
4) The likelihood the animal has come into contact with other susceptible animals prior to moving.

Sound management of the zoo of origin is key to the risk management. The biosecurity protocols of the originating zoo must be of a standard to prevent infectious disease transmission from outside animal populations and disease surveillance programmes should be effective enough to detect rabies infection should it occur. The standards of the zoos veterinary management can be determined by whether the premises has been approved against the standards set in EC Directive 92/65, often referred to as the 'Balai Directive'. Additionally quarantine or isolation procedures, disease surveillance and veterinary supervision at the receiving zoo are fundamental to preventing transmission to at risk populations post-import. Again, approval under EC Directive 92/65 is used as the basis for this assessment.

A further control point exists with the official veterinary services of both importing and exporting countries, which are responsible for supervising the health certification of the animal, inspections during transport and approval of quarantine premise. This is determined by whether the country is approved for the export of other live animals, such as livestock.

The final risk assessment containing the proposed mitigation factors and the effect they have on disease risk is shown below in Table 4

Table 4

Risk assessment for the importation of zoo animals into the United Kingom.

Animals	Risk Assessment with no risk management	Risk Assessment from Balai Approved Zoo to Balai Approved Zoo	Proposed Revised Import Conditions
Vampire Bats *(Desmodontidae)*	High	Medium	Permanent Quarantine
Chiroptera (not Desomodontidae); Canids, Felids, Mustelids, Procyonids, Viverridae, Ursids, Hyanids	Medium	Very Low	4 Month Quarantine required for Non-Approved Premises. Quarantine - Waived following risk assessment for Approved Premises
Primates	Low	Very Low	4 month Quarantine required for Non-Approved Premises. Quarantine - Waived following risk assessment for Approved Premises
Dermoptera Xenartha, Hyracoidea,	Very Low	Very Low	Quarantine - Waived following risk assessment

Eulipotyphyla, Marsupalia			
Lagomorpha	Low to Very Low	Very Low	EU trade - no Quarantine, no need for waiver. Originating outside EU - Quarantine Waived following risk assessment
Rodentia	Low	Very Low	Rodents (captive bred) destined for research institutes or zoo from research facility or zoo – no Quarantine 4 month Quarantine if not covered by authorisation for captive bred and not rabies free country
Pinnipeds	Very Low	Very Low	No quarantine

If the risk assessment demonstrates that the import of the specific animal and the risk mitigation measures put into place pre and post-import lead to a negligible or very low risk of the introduction of rabies into the UK then quarantine can be waived.

If the animal is moving between premises approved under Directive EC 92/65 then the risk is considered to be lower due to the high standards of veterinary management

and biosecurity. Therefore for species considered victims, there would be no quarantine necessary.

The final stage in the risk assessment is risk management and communication, which is completed through implementation of the revised policy.

Discussion

Risk assessment is a well-established and routinely used approach to policy making (Roberts et al, 2011). In this study the approach has been modified to create a structured and transparent framework for decision-making where evidence is very limited. The available evidence is presented clearly so that specific knowledge gaps are acknowledged and extrapolation from available evidence is explained. The use of an uncertainty rating within risk assessments is common practice and this can add a further level of detail. Risk mitigation actions can be assessed for effectiveness using the evidence presented by revisiting the risk analysis component of the methodology.

In this example, the evidence used originated from peer-reviewed literature, which is considered to be the most robust source of scientific evidence. However, the methodology can readily be adapted to include a range of other evidence sources such as grey literature, questionnaire results and expert opinion with the caveat that the source of the evidence remains clearly stated in the assessment.

The methodology facilitates rapid review following the identification or generation of new evidence. Simply by reviewing the risk assessment, the impact of new evidence can be tested. Conversely, the process identifies areas for potential research and investigation by highlighting knowledge gaps which are most significant.

This study is a rare example of official disease control policy affecting the health and welfare of zoo animals either through the impacts of the disease itself or the disease control interventions implemented. Similar risk assessments focused on non-domestic animals were undertaken during disease control policy development for Bluetongue Virus and Highly Pathogenic Avian Influenza (Defra, Unpublished) concerning animal movement restrictions, vaccination policy and culling policy.

There are many diseases that pose a risk to zoo animal populations, which are not regulated by government policy but could be managed by the zoo industry. Despite the operation of regional and international conservation breeding programmes and co-ordinated population management there are very few defined disease control policies or prevention programmes in place. It is likely that a significant cause of this is the lack of specific evidence. It is highly unlikely due to lack of funding, lack of specialist expertise, welfare concerns and poor public acceptance of experimental infection studies and the low number of clinical cases of each disease in zoo animals, that it will ever be possible to develop a comprehensive evidence base for the majority of the diseases which can have deleterious effects on zoo managed programmes.

Zoo decision makers need to develop skills and processes which address the lack of evidence and deal with uncertainty. Some work has begun to implement the methodologies in this study to diseases affecting breeding programmes such as Simian Immunodeficiency Virus in De Brazza monkeys *(Cercopithicus neglectus)* (Harley & Schmidt, 2013) and Herpes B viruses in *Macca sp.* (Hartley, Unpublished).

The continuation of the development of scientific based decision-making tools and methods to deal with uncertainty and lack of evidence is a far more feasible and practical approach to advance zoo management than relying on production of a comprehensive evidence base for many diseases in zoo species. This is supported by the recent publication of the IUCN manual of procedures for wildlife disease risk analysis (Jakob-Hoff, MacDiarmid, Lees, Miller, Travis, Kock, 2014)

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Chapter 3 - Approaches to Disease Risk Analysis in Wildlife Translocations for Conservation Purposes.

3.1 Authorship statement

Dr Anthony Sainsbury provided the data and information generated by his research group used to illustrate the concepts and methods described in the paper. I constructed the paper and wrote all the content.

3.2 Introduction to published paper

The paper published in this chapter (Hartley & Sainsbury 2017) critiques approaches to disease risk analysis in wildlife translocation projects. Data and examples from The Zoological Society of London's Disease Risk Analysis and Health Surveillance (DRAHS) project which, has been operating for 25 years, in partnership with Natural England and non-governmental organisations are used to illustrate the limitations of risk analysis and propose methods to respond to these difficulties.

The potential risk from diseases during conservation interventions such as translocations and reintroductions is well recognised (Cunningham, 1996; Kock, Woodford, & Rossiter, 2010; Leighton, 2002; Mathews, Moro, Strachan, Gelling, & Buller, 2006; Sainsbury & Vaughan-Higgins, 2012; Woodford & Rossiter, 1993)

Much work has been completed on developing systematic approaches to assessing disease risk and producing guidelines on their application for conservation interventions (Sainsbury, Armstrong, & Ewen, 2012) (Jakob-Hoff et al., 2014; Miller, 2007). These processes are all derived from the original concepts of Covello & Merkhoher, (1993) and the OIE framework (Murray, 2004) and follow the same basic pathway and approach as the latter, consistently allowing for shared understanding of the development process and therefore interpretation. There is a spectrum of approaches to application and implementation due to both financial and expertise resource constraints and the integration of the risk analysis into decision making processes, within the project and legislatively (Sainsbury et al., 2012). It is recognised that the process is in its infancy and will develop as more experience is gained and different scenarios are assessed (Jakob-Hoff et al., 2014; Sainsbury et al., 2012) this

necessitates that experiences and techniques are shared. In order to achieve this, the paper in this chapter (Hartley & Sainsbury, 2017) was presented at an international conference held in London in May 2015 and was included in a special issue of the journal Ecohealth.

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3.4 Published paper

Approaches to Disease Risk Analysis in Wildlife Translocations for Conservation Purposes.

M. Hartley & A.W.Sainsbury

Abstract

Wildlife is intentionally and unintentionally translocated regularly carrying with it a range of parasites and pathogens. There are numerous examples of disease outbreaks originating from translocated animals. Managers of conservation projects, which involve translocating wildlife have a responsibility to protect humans, domestic animals, other wildlife and the ecosystem from negative effects of disease carried by the focus species. There is a significant lack of data available on the susceptibility, epidemiology and impacts of pathogens in wildlife populations making preventative actions challenging.

Risk analysis has been developed to provide an objective, repeatable, transparent and documented assessment of the risks posed by a course of action. Standardised techniques have been developed and are utilised routinely to aid decision making. It is a tool used to guide policy making and disease control planning by governments and international organisations such as the OIE (World Organisation for Animal Health). Qualitative risk analysis is particularly useful in fields when quantitative data is lacking. Risk analysis has been developed for use in animal health risk management and subsequently adapted for wildlife disease management scenarios, cumulating in publication of the OIE/IUCN Manual of Procedures for Wildlife Disease Risk Analysis (2014).

This paper considers further modification of risk analysis methods for wildlife translocations undertaken for conservation purposes. The challenges of these specific scenarios including hazard identification, multiple epidemiological pathways and data

gaps are addressed and tools which could improve the usefulness of the technique, such as developing scenario trees and rating uncertainty are proposed.

Introduction

Risk analysis processes have been developed to provide an objective, repeatable, transparent and documented assessment of the risks posed by a course of action or chain of decisions. Standardised techniques have been developed and are utilised routinely to aid decision-making by governments and international organisations such as the OIE (World Organisation for Animal Health) in assessing the risk from disease to humans, domestic animals and wildlife.

Wildlife managers and decision makers are increasingly adopting these processes to aide management of disease threats to conservation interventions, such as re-introductions, rehabilitation and release or wild-to-wild translocations. The ability to use structured, reasoned, recognized qualitative approaches is particularly useful when evidence and data is lacking which is common when working with wildlife. Several different systems and formats are in use but all broadly follow the principles of risk analysis advocated by Covello and Merkhofer (1993) in their treatise on across-discipline risk analysis for the above benefits to be realised.
This paper reviews approaches to disease risk analysis in wildlife translocation projects addressing reasons for undertaking assessments, potential sources of information and personnel involved. There are always multiple hazards, which complicates the traditional risk analysis approach, and paucity of information on the identity and geographical distribution of parasites hampers hazard identification (Sainsbury and Vaughan-Higgins 2012).

The Zoological Society of London's Disease Risk Analysis and Health Surveillance (DRAHS) project has been operating for 25 years, in partnership with Natural England and non-governmental organisations, to assess and respond to disease risks associated with interventions undertaken for the national Species Recovery Programme for native wildlife. Our experience from conducting these disease risk analyses is used to describe the limitations of the analysis and propose some methods to respond to these difficulties.

Disease impacts of wildlife translocations.

Translocation is the intentional movement of living organisms from one geographical area for free release into another with the object of establishing, re-establishing or augmenting a population (Kock et al, 2010).

The Natural England Species Recovery Programme has utilised a range of different translocation methods over the last 25 years. These include (i) captive breeding and release to supplement diminished populations for example in hazel dormice (*Muscardinus avellanarius*) and corncrakes (*Crex crex*), (ii) Importation of animals from other countries to re-establish populations in the UK such as for the pool frog (*Pelophylax lessonae*) and short-haired bumble bee (*Bombus subterraneus*) or (iii) wild to wild translocations to establish new local populations and increase a species' range such as for wart-biter cricket (*Decticus verrucivorus***)** and smooth snake **(***Coronella austriaca***).**

In the past wildlife translocations were commonly undertaken without thought to disease issues (Griffin et al, 1993). Indeed, the DRAHS project was established in 1989 many years after the first translocations had been undertaken for the Species Recovery Programme.

The potential impact of infectious disease on the outcome of wildlife conservation interventions has only recently been recognised. Disease may be seen in the focus species or in other wild or domestic species or humans at the site of the intervention or may have wider environmental or eco-system effects. The impacts of a disease outbreak may affect a wide range of stakeholders such as government, farmers, local residents and businesses. For example an unauthorised introduction of European beavers posed the potential risk of introducing the zoonotic pathogen *Echinococcus multilocularis* to the UK (Simpson et al, 2011).

Where the translocated species originates from an ex-situ population, there is a risk that it acquires, and becomes a symptomless carrier of, infectious agents novel to the

destination. Animals in ex-situ environments may be mixed with species from unrelated geographic origins and as a result may be exposed to exotic (alien) pathogens and to infectious agents transmitted by carers and other humans. Furthermore, captivity, or management of ex-situ populations, subjects species to stress resulting in immunosuppression and increased susceptibility to disease (Kock et al, 2010). For example, hazel dormice were exposed to a suspected novel cestode species in captivity prior to reintroduction in England (Peniche et al, 2017).

Translocated animals may lack acquired immunity or resistance to the infectious agents which will challenge them at the release site. Many diseases and parasites are highly localised in distribution as a result of the specific ecological requirements of the pathogen and/or vectors (Kock et al, 2010). For example red squirrels (*Sciurus vulgaris*) reintroduced in England were exposed to squirrelpox virus (harboured by the alien invasive grey squirrel, *Sciurus carolinensis*) at the destination reintroduction site resulting in a severe squirrelpox disease outbreak (Carroll et al 2009).

These examples highlight the burden of responsibility that managers of conservation interventions have when planning a project and the importance of a robust, transparent and comprehensive process to identify potential disease risks and to manage those risks appropriately and effectively.

What is disease risk analysis?

Risk analysis is a tool intended to provide decision-makers with an objective, repeatable and documented assessment of the risks posed by a particular course of action (MacDiarmid, 1997). As the approach has developed and diversified a more specific disease focused definition was proposed by Jakob-Hoff and others (2014) who stated that: disease risk analysis is a structured, evidence- based process that can help decision making in the face of uncertainty and determine the potential impact of infectious and non-infectious diseases on ecosystems, wildlife, domestic animals and people. The authors explained how the results from disease risk analysis can be used to help decision makers to consider an evidence-based range of options for the prevention and mitigation of disease in the population(s) under consideration.

Development of disease risk analysis

Disease risk analysis was developed by adapting environmental risk analysis techniques. The World Organisation for Animal Health (OIE) developed the OIE Risk Analysis Framework (Murray et al, 2004). This has formed the basis of disease risk analysis systems developed by other organisation such as the Department of Environment, Food and Rural Affairs and Biosecurity Authority, Ministry of Agriculture, New Zealand. The framework has been used for a range of scenarios beyond import risk analysis including domestic animal notifiable disease incursion, wildlife disease control (Hartley, 2009; Hartley et al, 2012) and pest species entry (Tana et al, 2003). An example of a risk analysis system, including the risk assessment process is shown in Figure 1.

Davidson and Nettles (1992) Leighton (2002), Armstrong et al. (2003), and Miller (2007) devised qualitative methods for assessing the risks of disease associated with wildlife translocations. Armstrong et al. (2003) and Miller (2007) also devised quantitative methods. In 2014 the IUCN and OIE jointly published the Manual of Procedures for Wildlife Disease Risk Analysis, which collated and consolidated current knowledge and provided a framework for developing, interpreting and utilizing disease risk analysis in wildlife conservation.

Disease risk analysis approaches and modifications for wildlife translocation.

The first stage in any risk analysis is to determine the problem or issue, which is to be addressed, otherwise known as the ‘risk question’. The risk question needs to clearly establish the goals, scope and focus of the analysis and will depend on who has commissioned the work and is the risk manager. The results of disease risk analysis for wildlife translocations may be used by the conservation team running the project, to identify risks to the threatened species of focus and increase the likelihood of project success. A risk analysis commissioned by a governmental agency authorising and licensing a wildlife translocation may prioritise potential risks to other wildlife, including at the destination site, whereas public health officials will primarily be interested in

zoonotic risks associated with the translocation. Government agricultural agencies, farmers and landowners will have a focus on potential risks to domestic animals and agricultural production (Hartley & Gill, 2010).

In practice, a single disease risk analysis is likely to be required to meet the requirements of all of these stakeholders. The DRAHS project risk analysis, when commissioned at the initiation of a project, will not only guide resources and activities of the Natural England Species Recovery Programme but contribute to official licensing decisions and cross-governmental support.

Even when focused solely on threatened species there are a wide range of scenarios in which disease risk analysis could be used including (i) prior to commencing a re-introduction programme (Sainsbury et al, 2012), (ii) in response to a specific disease identified during the course of a project or (iii) in response to an epidemiological investigation of unknown disease in the focus species. Table 1 describes how DRA, disease risk management (DRM) and post-release health surveillance (PRHS) has been built into the health and disease monitoring of species translocations covered by the DRAHS project.

Defining the risk question is sometimes included within the first step of the risk analysis framework along with hazard identification (e.g. US Environmental Protection Agency 1998). However, in some circumstances the risk managers may define the problem description before commissioning the work and appointing risk assessors. Conducting separate problem description and hazard identification exercises helps to protect the scientific evaluation of risk from being overly influenced by political and social issues that may arise during problem description (US Environmental Protection Agency 1998).

Once the risk question has been determined, hazard Identification is undertaken. A hazard can be defined as a biological, chemical or physical agent in, or a condition of an animal, or an animal product with the potential to cause an adverse effect on health (Jakob-Hoff et al, 2014).

Generally in traditional domestic animal import and incursion disease risk analysis, developing the risk question will result in two different scenarios. Either the problem is focused on a single risk pathway but involves multiple hazards, for example risks posed to consumers of legally imported cooked chicken from outside of Europe or the problem is specific to one well defined hazard and there are multiple risk pathways, for example rabies entering the country in domestic dogs. However this is very rarely the situation when considering risks posed by wildlife translocations. Risk assessors working with wildlife health problems have lead the development of techniques for working with multiple hazards and multiple risk pathways in a single risk analysis (Hartley, 2009: Hartley et al, 2012, Sainsbury et al, 2012) .

Once a problem has been described it will be possible to estimate the level of detail required in the risk analysis. Criteria could be established for ranking the importance of each hazard and its possible direct and indirect consequences within the bounds of the defined problem. This prioritisation step is important as the number of pathogens harboured by every organism could potentially make the risk analysis enormous and therefore unrealistic and unachievable with the resources available. For example, Neimanis and Leighton (2004) analyzed qualitatively the risks of disease from 122 species of parasites associated with translocation of wild Eastern Turkeys *(Meleagris gallopavo)* to Canada. A qualitative analysis of risk of disease from so many parasites is difficult and time consuming, and a quantitative analysis is not feasible (Sainsbury et al. 2012). When undertaking hazard identification during preparations to translocate elk *(Cervus elaphus)* Corn & Nettles (2001) identified 190 potential pathogens but prioritised 16 hazards considered to be of a higher risk than negligible or very low. DRAHS conducted qualitative analysis for 26 source, destination, carrier and transport hazards for the short-haired bumblebee *Bombus subterraneus* translocation (Vaughan-Higgins et al 2012); 18 carrier, transport, source zoonotic and destination hazards for smooth snake *Coronella austriaca* translocation (and discounted a further 22 suspected hazards) (Masters and Sainsbury 2011); 16 carrier, source, destination, zoonotic and population hazards for proposed translocation of the European adder *Vipera berus* (Beckmann et al 2014a) and 21 source and destination hazards for the proposed translocation of white-tailed sea eagle *Haliaeetus leucocephalus* from Poland to England (Sainsbury et al 2010).

Prioritisation of hazards is extremely difficult in wildlife translocation scenarios as the epidemiology of many known pathogens is poorly understood and unknown pathogens may be present but undetected. Many catastrophic disease outbreaks as a consequence of translocation have been associated with previously unknown parasites (Bobadilla et al 2015; Walker et al 2008). It is difficult to predict the consequences of infection in immunologically naïve animals and disease surveillance data is limited so the presence or absence of a pathogen in the source population or in animals at the destination site may not be known.

In response to this, in the DRAHS project, Sainsbury and others (2012) modified the definition of a hazard to better reflect the epidemiological scenarios of wildlife translocation. Host–parasite encounters may occur at several stages of the translocation pathway, noninfectious diseases can have negative effects on the translocated population and other stressors may trigger disease. Previous definitions of a hazard require an infectious agent to cause harm (Murray et al, 2004). Understanding of parasite pathogenicity in wild animals is limited, but given knowledge of the threat posed by non-native invasive parasites, Sainsbury et al, (2012) considered that novelty of an infectious agent to the host is a sufficient reason to classify the infectious agent as hazardous in the absence of information on pathogenicity. These authors defined hazards on the basis of whether a parasite was new to a host, on the immunological interactions between host and parasite, the effect of stressors on these interactions or the ability of the parasite to affect populations.

Once the hazard identification process has been completed the risk pathways or scenario trees can be developed. These graphical models identify the various factors involved in the risk assessment process and the various biological pathways of expected events resulting in the occurrence of a defined outcome. Thus, these visual pictures provide a useful conceptual framework for the risk assessment, facilitate transparency and aid in communicating the risks to the various stakeholders, in a simple, logical and reasoned framework (Macdiarmid & Pharo, 2003). Scenario trees can be constructed for the release, exposure and consequence assessment steps in the risk assessment process: release. An example is provided in Figure 2.

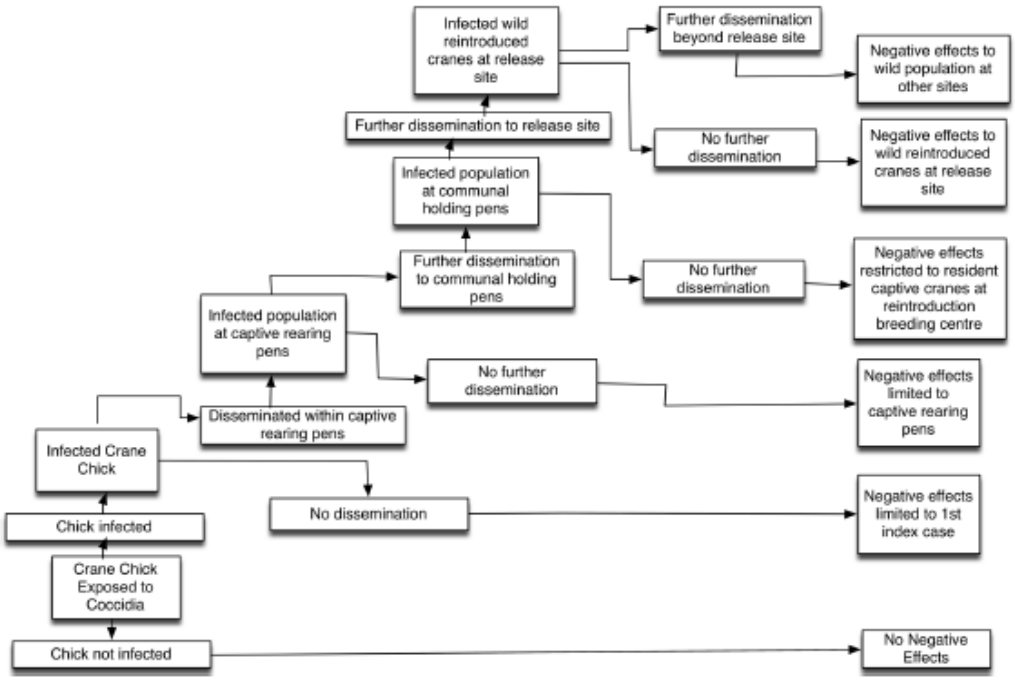

Figure 2 Scenario tree illustrating the effects of coccidia infection on eurasian cranes reintroduced to England from Germany. Modified from Sainsbury et al. (2012).

Wildlife translocation risk assessment should follow the basic scientifically accepted approaches which have been developed to ensure that the output is valid, transparent and accepted. The framework for risk assessment, being composed of release, exposure, and consequence assessments, is established and described by several authors whom have adhered to the same concepts with modification to the particular scenarios in their individual fields (Covello and Merkhofer,1993; Murray et al, 2004; Jakob-Hoff et al, 2014, Sainsbury et al, 2012) A model of risk assessment is shown in Figure 1.

Import disease risk assessment as advocated by the OIE uses international borders as the division between source and destination environments and thus limits the possibility of hazard release and exposure (Murray et al, 2004). Wild animals and their parasites are restricted in their distribution by ecological barriers (e.g., niche separation) and topographic barriers (e.g., mountain ranges or seas) rather than political barriers and this must be reflected in the risk assessment (Sainsbury and Vaughan-Higgins, 2012).

In order to ensure utmost transparency and to aide development of the risk assessment, a risk table is a useful tool. This is particularly true where multiple hazards and multiple risk pathways occur. A risk table shows the steps in the risk pathway, summarises evidence, states the release, exposure and consequence assessment and produces a final risk estimation for the hazard or pathway (Hartley, 2009; Hartley et al, 2012; Jakob-Hoff et al, 2014).

The risk assessment can be developed using a wide range of additional tools, ranging from simple diagrams and spreadsheets to more clearly present the data, to bespoke software which develops quantitative assessments using data collected, to complex models which explore variability and uncertainty. A comprehensive review of available risk assessment tools is presented by Jakob-Hoff and others (2014). The use of these tools does not divert from the risk analysis framework but merely contributes to enabling risk conclusions to be reached and justified. In many wild animal translocation scenarios the lack of understanding of hazard epidemiology prevents accurate calculation of probability of disease occurrence and limits the value of the tools.

Risk assessment is an iterative process. As the assessment is built it may be recognised that some potential hazards have been missed or one of the risk pathways is not as first thought. For example black queen cell virus (BQCV) was detected in short-haired bumblebees in Sweden in the second year of the reintroduction programme but had not previously been considered a hazard. The DRA was immediately updated with a risk assessment of BQCV as a source hazard (Shotton et al 2015). It is important to modify the analysis to represent the best current knowledge. This modification may occur throughout the life of a translocation project as new information from the literature or the project itself becomes available. In the DRAHS project the risk assessments may be reviewed many times during a project and are often reviewed on an annual or bi-annual basis.

In addition post-translocation disease surveillance, disease outbreak investigation findings and post-mortem examination results from the focus species or other animals at the translocation site or the population of origin are fed back into the risk assessment. For example, in 2013 eleven corncrakes with metabolic bone disease were identified at their pre-release health examination and changes made to their diet

over the following 18 months to try to reduce the incidence (Beckmann et al 2014b). The risk of ranaviral disease in pool frogs was re-analysed in 2015 because further data was available on the distribution of the virus in the UK (Shotton and Sainsbury 2015). This adaptive and ongoing risk analysis is essential to be able to respond to the dynamic ecology of the populations that are worked with on this project and continually improves the performance and accuracy of the risk analysis.

Who should be involved ?

In developing risk assessments a broad range of expertise may be required such as epidemiologists, ecologists, diagnostic scientists and conservation field staff. It is unlikely that all this expertise will be incorporated in a single 'unit'. Therefore risk analysis should be treated as a project with the people having the necessary skills being assembled into the team as required and consulted as necessary.

It has been stated that in order to ensure the risk assessment process is not influenced by personal or public pressures those undertaking the assessment should not be decision makers or be influenced by decision makers (NRC, 1994; Leighton, 2002). While this might be a long term ideal, in reality this is not practical as many people, especially in the wildlife field, have multiple roles and responsibilities and differing influence on decision-making. Indeed decision makers may contribute important evidence in relation to likelihood and feasibility of courses of action, which will influence the translocation pathway chosen. Jakob-Hoff and others (2014) take an alternative approach and recommend that ideally a well- prepared and -funded workshop, in which an appropriate range of experts, stakeholders and decision makers are gathered for a facilitated, structured review and analysis of the scenario, is organised.

In the DRAHS project wildlife veterinarians, epidemiologists, diagnostic scientists, pathologists and ecologists from ZSL work together with ecologists from Natural England to produce the DRA and DRM. A bi-annual steering committee composed of decision makers, partner representatives and technical staff with ecological,

veterinary and policy experience contribute to the development and review of DRAs and challenge the risk assessments. This steering committee will also engage input from other sources such as licensing and animal health officers as needed.

Information required

In order to undertake a comprehensive risk assessment a wide variety of information is required. This includes data on the species and populations of animals and parasites (including pathogens) in the source and destination populations, mechanisms of spread, potential impact, non-infectious hazards, preventative health procedures such as quarantine and pathogen screening proposed by the translocation team and post-release monitoring to be undertaken. Broader information on the ecology of the species being translocated and ecosystem such as natural geographical and ecological barriers, habitat, climate, and vegetation type may be important. Gathering this information will require a thorough review of the published literature and interrogation of unpublished sources of information such as from diagnostic laboratories, experts, researchers and field reports.

As there is invariably a paucity of data in wildlife translocation risk analysis the use of a wide range of stakeholder expert opinion is useful. However, consultation with experts should be done in a formal and structured manner such as a facilitated workshop or a questionnaire so that the information collected is equally balanced and transparently presented in the risk analysis. Expert opinion can be developed further to help develop probability data for both qualitative and quantitative risk analysis (Murray et al, 2004).

Information for risk analysis for the DRAHS project comes from different sources depending on the nature of the project and the purpose for which the DRA is being undertaken. Sources may include peer-reviewed literature, grey literature reports from other translocation projects, expert opinion or active parasite surveillance from the project itself, for example in conducting the DRA for the short-haired bumblebee (Vaughan-Higgins et al 2012).

Quantitative versus Qualitative Analysis

In other fields, such as environmental contamination assessment, mathematical modelling is used to generate numerical estimates of probability and the extent of negative consequences. In order to address scenarios where data is not available to feed the models qualitative approaches have been introduced and have been by far the most frequently used approach for wildlife disease risk analysis.

Accurate estimates of parameters as fundamental as prevalence of infection, incubation period, duration of infection, and the size and distribution of wildlife populations rarely exist for wild animals and their parasites. This extreme rarity of numerical data means qualitative risk assessment is probably as accurate as quantitative risk assessment in wildlife translocation.

In 25 years of the DRAHS project it has never been possible to undertake a quantitative risk assessment as reliable numerical data was not available for the 17 species for which DRA or DRM has been conducted as a component of the Species Recovery Programme.

It should be remembered that the term qualitative risk assessment does not mean that no numerical data is used to assess the risk but that the risk estimation is presented in words that describe the evaluated risk. The advantage of the risk assessment being presented in qualitative terms is that the use of plain language and logic is more understandable by a wider range of stakeholders and decision makers.

Uncertainty and Subjectivity

Historically the view was taken that if there is insufficient information the risk assessment process should be halted (Leighton, 2002). However, in the field of wildlife health such an approach is not realistic as invariably there are large gaps in data and so few assessments could be completed. Extrapolations can be made from the best available information. It is important to state clearly the areas and extent of the

uncertainty. This is almost as important as giving estimates of risk, particularly in the early stages of assessment when uncertainties may be large and the data poor.

Some risk assessors include an explanation of the reasons for uncertainty at each stage in the risk pathway (Hartley, 2009; Hartley et al, 2012) which aides in transparency and enables risk managers to make separate decisions on different components of the problem where the level of acceptable risks may be different.

Disease risk analysts have not, to date, used mathematical or modelling approaches to address uncertainty. One approach that could be considered is information gap theory. This was invented by Ben Haim (2001) to assist in decision making when there are severe knowledge gaps and when probabilistic models of uncertainty are unreliable, inappropriate or unavailable. It requires three main elements; a mathematical process model, a performance requirement and a model for uncertainty. These techniques have not been used due to the lack of collaboration between disease experts and modelling experts and the fact that disease risk analysis for translocation does not have a single desired or preferred outcome but many different possible outcomes which means that models would need to be very complex and therefore very time consuming.

The risk assessment can highlight specific data inadequacies and deficiencies and allow sensible targeting of resources to collect essential data to improve knowledge. Therefore lack of good data is not a good argument for not undertaking a risk assessment (Wooldridge, 2000). This is certainly true in the DRAHS project where risk analyses are reviewed by the steering committee on a bi-annual basis and decisions made on resource priorities for work over the next six-months. The DRA for pool frog reintroduction recommended the collection of data on ranaviral distribution and presence (Shotton and Sainsbury 2015), and data is currently being collected.

In theory risk analysis is an objective process. The reality is that in wildlife translocation disease risk analysis there are often so few data available that the analyst has to substitute value judgements for facts. This is supported by the common use of expert opinion.

The use of expert opinion can generate uncertainty where there is expert disagreement. In this case it is necessary to explore the implication of the judgements to determine their impact on the final conclusions. Experts may disagree on the body of knowledge or draw different inferences from an agreed body of knowledge. In either case this should be reflected in the risk assessment. Much has been written concerning structured methods of eliciting expert opinion for decision making processes (Clemen 2001; Meyer & Booker, 1991) all of which is relevant to using experts as a source of information for disease risk analysis.

Risk assessment may be criticised because some of its inputs are based on assumptions. However, all decision making is based on assumptions, and uncertainty and subjectivity do not mean that valid conclusions cannot be drawn. Although many of the inputs of a risk assessment are surrounded by uncertainty, one may be able to have confidence that the 'true risk' is unlikely to exceed the estimate resulting from a careful and conservative analysis (MacDiarmid 2001).

Wildlife translocation disease risk assessments are seldom completely objective and therefore transparency, by recording and highlighting uncertainty and subjective decisions and the basis that these decisions have been reached is essential. In this way, as more data become available or the project is actioned and outcomes are known then the risk assessment can be revisited and revised in light of the new information.

Disease Risk Management

Disease risk management is the process of identifying measures that can be applied to the problem which reduce the level of risk from disease. In some circumstances risk management is not the role of the risk analyst, they are merely asked to assess the risk but not revise the assessment by proposing management actions. For example when determining import policy for rabies susceptible zoo animals, epidemiologists and zoo veterinarians developed the risk assessment whilst the import policy was determined by policy officials using the risk assessment as an evidence base (Hartley & Roberts, 2015). In wildlife translocation risk analysis it is more common for the risk

assessment to be used as a tool to develop risk management actions. Consideration of risk management actions will help prioritise the hazards and redefine the acceptable levels of risk. A high risk hazard may be readily managed and thus the risk reduced allowing a decision to proceed with the intervention to be made. The description and particularly visualisation of the risk pathway greatly aides the identification of critical control points where risk management actions can be applied (Hartley & Schmidt, 2013) and was used in the DRA for the reintroduction of the cirl bunting (McGill and Sainsbury 2007).

The risk management options need to be assessed for feasibility and affordability so that they can be accepted or rejected by decision makers. Including risk management actions into a wildlife translocation risk assessment begins to merge the role of risk analyst and decision maker, which is not encouraged in many fields such as environmental protection and veterinary policy making. However, in reality wildlife translocation teams are small and integrated. The team manages all aspects of the project and therefore have the expertise to be able to make sound judgements on risk management. The inclusion of risk management options and their impact on the risks considerably expands the relevance and usefulness of the risk analysis as a practical tool.

In the DRAHS project, the veterinarians and scientists who complete the disease risk analysis also undertake veterinary care and disease surveillance activities on the translocation project. The understanding of the identified risks, practical and realistic risk management interventions and disease surveillance data collected allows for the implementation of comprehensive risk management procedures. For example very detailed risk management procedures have been implemented for the corncrake reintroduction project, which has proceeded since 2001, in response to the changing risk of coccidial disease year on year determined through disease surveillance (Sainsbury and Jaffe 2015).

Risk Analysis as a tool for decision making

Risk analysis does not give a single correct answer to a problem but is a step by step exercise using facts and data plus opinions and judgements from a broad variety of perspectives (Woodridge 2000).

One of the most difficult problems faced by decision makers is that of deciding what constitutes an acceptable risk. In some situations it may be relatively easy to show the benefits as wells as the risks associated with the course of action. In other situations it may be difficult to attain agreement on what constitutes an acceptable risk even in situations where risk can be quantified objectively. Knowledge of costs and benefits are seldom shared equally between all stakeholders who will therefore have different perspectives of acceptability (MacDiarmid, 2000).

Zero risk is seldom, if ever, attainable and some degree of risk is unavoidable. For this reason, deciding whether or not a particular risk is acceptable is generally a societal or political decision because the benefits of a particular activity for one stakeholder group may have adverse consequences for another (MacDiarmid and Pharo 2003; Thrusfield 2007). In a pool frog translocation, the risk assessors decided that more data on the presence or absence of potentially alien parasites in the source population should be sought through screening, before translocation proceeded. Only 33 adult or juvenile pool frogs had been tested for alien parasites from the source population and extinctions of amphibians due to disease associated with alien parasites had been reported (McGill et al 2005). However the pool frog reintroduction steering committee, having considered the costs and benefits, decided to proceed with translocation.

Disease risk analysis is only part of the decision making process when considering whether a wildlife translocation should proceed. Financial costs, public support, political approval and stakeholder endorsement will all be other contributors. It may be necessary to make difficult trade-offs between the biologically or epidemiologically optimal decision and these other drivers. This is one of the many values of risk analysis as these decisions can be transparently and comprehensively assessed in an evidence-based, scientifically accepted process.

In the DRAHS project, the results of the disease risk analysis have led to the suspension of two reintroductions and the relocation of the rearing facility for a third. The reintroduction of barberry carpet moths was discouraged because the moths had been in contact with exotic lepidoptera (Sainsbury 2007) and no reintroduction using that captive colony has taken place. The barrier between captive adders and exotic vipers was found to be inadequate and the DRA suggested that the captive adders should not be released and another approach to conservation should be taken (Beckmann et al 2014a). None of the captive adders were released. In the cirl bunting project and greatest risk from disease was attributed to housing the cirl buntings in a zoological collection and a recommendation made to move the captive reared birds to a facility distant from the zoo (McGill and Sainsbury 2007). A new cirl bunting rearing facility was created close to the reintroduction site (Fountain et al 2016). In other cases the DRA or DRM has fundamentally influenced the management of the project, for example the elimination of suspected alien parasites in the dormouse project already mentioned, the risk management actions undertaken for corncrakes, and the screening of cranes for inclusion body disease virus prior to the reintroduction commencing (Sainsbury and Vaughan-Higgins 2012). To date, no major zoonotic or agricultural significant diseases have been identified in DRAHS projects as high risk of disease and greater repercussions might be expected with such infectious agents. High risk hazards identified have all impacted on the project focus species and closely related sympatric species.

Conclusions

Wildlife disease risk analysis processes are still very much developing and there are still challenges to address. Some do not consider risk analysis as a valid scientific methodology. One editorial referred to the discipline as a ‘fad’ related more closely to developing a bureaucratic excuse that few outsiders can fathom than to intelligent decision making (Anderson, 1994).

Indeed, very few animal health risk analyses have been published in peer-review literature (MacDiarmid, 2000) and even fewer wildlife disease risk analyses have been published, although some examples do exist (Hartley et al, 2009; Hartley et al, 2012).

This lack of recognition and difficulty in publication means that relatively few scientists are working in the field of wildlife disease risk analysis creating a shortage of expertise. These factors conversely affect the level of funding available to support experts to undertake wildlife disease risk analysis.

Major steps forward have been achieved through the recent publication of guidelines for wildlife disease risk analysis (Jakob-Hoff et al, 2014). This publication confirms general recognition of the usefulness of this tool especially in a field where data is severely lacking and difficult and expensive to generate. Although these guidelines provide an important review and a description of the approaches and tools available to risk analysts, they do not provide a single standardised approach as the field of wildlife disease is so diverse and the problems being assessed so varied.

It may be more feasible to develop a standardised and structured approach to disease risk analysis for conservation translocations as the scope and purpose of the risk analysis is better defined. Risk analysts are also likely to also be risk managers and so the priorities and drivers of risk management are less complex. Some authors have described their approach to translocation risk analysis (Corn et al, 2001; Davidson et al, 1992; Neimanis et al, 2004; Sainsbury et al, 2012; Sainsbury et al, In Press). This paper reviews the important features of risk analysis and discusses how refinements of the process, made through practical application in the wildlife field, could be implemented specifically for conservation translocation disease risk analysis. As recognition and acceptance of the role of risk analysis as an important tool in evidence-based decision making develops, the limitations of finance and available expertise must be overcome so that disease risk analysis is required as a fundamental component of planning, authorisation and implementation of conservation translocation so that disease risks are thoroughly investigated, assessed and managed so the risk of repeating the mistakes of the past is reduced.

Table 1. Overview of Disease Risk Analysis (DRA), Disease Risk Management (DRM), and Post-release Health Surveillance (PRHS) conducted by the Disease Risk Analysis and Health Surveillance (DRAHS) project for species subject to translocation in England.

Species	**Translocation Description**	**Scenario Disease Risk Analysis (DRA) Undertaken**	**Disease risk management (DRM) actions**	**Review process for Disease Risk Analysis**
Corncrake *Crex crex*	Captive breeding and release from two zoological collections	DRA not completed - programme initiated before DRA was built into DRAHS project.	Quarantine. Biosecurity protocol; Specific actions undertaken to combat diagnosed disease, for example coccidiosis, disease associated with *Enterococcus hirae*, metabolic bone disease. Pre-release health assessment.	Annual revision of DRM protocols based on results.
Hazel Dormice *Musardinus avellanarius*	Captive breeding and release from over ten	DRA not completed because programme	Quarantine. Biosecurity protocol; Pre-release health	Annual revision of DRM and PRHS

	captive collections	initiated before DRA was built into DRAHS project.	assessment; elimination of suspected alien cestode parasite; therapeutic treatment for native parasites; and post release health surveillance (PRHS)	protocols based on results.
Sand Lizard *Lacerta agilis*	Captive breeding and release from multiple captive collections	DRA completed 32 years after the first reintroduction.	Quarantine; biosecurity protocol; Pre-release health assessment, therapeutic treatment to reduce nematode infestation; post-release health surveillance	Annual revision of DRM and PRHS protocols based on results.
Eurasion crane *Grus grus*	Import of eggs from Germany and captive rearing and release	DRA during planning stages of project	Quarantine; biosecurity protocol; Pre-release screening for inclusion body disease virus of	Continuous review of DRM and PRHS protocols based on results.

			cranes; pre-release health assessment; disease control for example preventive coccidial treatment; post-release health surveillance.	
Wart-biter Cricket *Decticus verrucivorus*	Wild to wild translocations	DRA during planning stages	Quarantine; Pre-release health assessment; Post- release disease surveillance	Annual review of DRM PRHS protocols based on results
Fen raft Spider *Dolomedes plantarius*	Captive breeding and release from multiple zoos	Reintroduction had started before a DRA could be completed.	Quarantine; biosecurity and hygiene protocol; pre-release health assessment;	Annual review of DRM protocol based on results
Smooth Snake *Coronella austriaca*	Wild to wild translocation s	DRA completed 40 years after translocation programme started	Quarantine; biosecurity protocols; pre-release health assessment; post release health surveillance	Annual review of DRM PRHS protocol based on results

Pool frog *Pelophylax lessonae*	Wild to wild translocation across geographical and ecological barriers from Sweden to England. Wild to wild translocation from first site in UK to second site.	DRA completed before first translocation. DRA revised prior to translocation to second site.	Quarantine; biosecurity protocol; pre-release health assessment; post-release health surveillance of pool frogs and sympatric amphibian species	Annual review of DRM PRHS protocols
European adder *Vipera berus*	Proposed captive breeding and reintroduction. Reintroduction did not proceed.	DRA completed. Revision of reintroduction plan recommended.	No reintroduction	Not applicable.
Short-haired bumblebee *Bombus subterraneus*	Wild to wild translocation from Sweden to England across geographical and ecological barrier	DRA completed prior to translocation. DRA revised when new infectious agents detected in source population or new hazard suspected.	Quarantine; biosecurity protocols; screening for alien parasites prior to release; bees with alien parasites not released (may be returned to source)	Annual review of DRM and PRHS protocols based on results.

Cirl bunting *Emberiza cirlus*	Initial plan to captive breed in zoo ceased following DRA. Wild to wild translocation.	DRA completed before translocation.	Quarantine. Biosecurity protocol. Pre-release health assessment. Preventive therapeutic treatment for coccidial parasites; post-release health surveillance	Annual review of DRM PRHS protocols.
Red kite *Milvus milvus*	Translocation eggs and chicks from Sweden and Spain across ecological and geographical barriers.	No DRA – programme commenced prior to implementation of DRA in DRAHS project.	Quarantine; biosecurity protocols; pre-release health assessment; preventive treatment for parasite infestations; post-release health surveillance	Annual review of DRM PRHS protocols
White-tailed sea eagle *Haliaeetus leucocephalus*	Proposed reintroduction from Poland. No reintroduction occurred.	DRA completed prior to proposed reintroduction.	Quarantine; biosecurity protocol; pre-release assessment; post-release health	Not applicable

			surveillance protocol written	
Fishers estuarine moth *Gortyna borelii lunata*	Captive breeding in a zoological collection and reintroduction.	Reintroduction commenced prior to DRAHS involvement. No DRA	Quarantine; biosecurity protocols; pre-release health assessment; post-release health surveillance	Annual review of DRM PRHS protocols
Red squirrel *Sciurus vulgaris*	Trial wild to wild translocation	Translocation occurred before DRAHS integrated DRA into monitoring programme	Quarantine; biosecurity protocols; pre-release health assessment; therapeutic preventive treatment for parasites; post-release health surveillance	Annual review of DRM PRHS protocol.
Barbary carpet moth	Proposed captive breeding and reintroduction. Reintroduction did not occur following DRA	DRA completed prior to proposed reintroduction.	Not applicable	Not applicable
Red-barbed ant *Formica rufibarbis*	Captive breeding and reintroduction from two	DRA completed prior to translocation.	Quarantine; biosecurity protocols; pre-release health assessment;	Annual review of DRM PRHS protocol

	captive collections		post-release health surveillance	based on results.
Field cricket *Gryllus campestris*	Captive breeding and reintroduction from one captive collection	DRA completed after reintroduction commenced.	Quarantine; biosecurity protocols; pre-release suspected alien parasite screening; post-release health surveillance	Annual review of DRM PRHS protocol.

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Chapter 4 – Use of Risk Analysis Techniques for Decision Making. Assessment and Mitigation Process for Disease Risks Associated with Wildlife Management and Conservation Interventions.

4.1 Authorship Statement

Dr Elaine Gill headed the team that would be using the product described in this paper and so provided legislative and delivery input into its production. The risk tool and the surrounding justifications for the decision-making processes are solely my work

4.2 Introduction to published paper

The paper in this chapter (Hartley & Gill, 2010) describes the use of risk analysis techniques applied in a structured process to wildlife licensing. The paper indicates when risk assessment is required to inform decision making and uses a risk scenario concept to present a transparent and consistent basis for wildlife license approval in England.

Wildlife capture, translocation or release may be instigated for a number of reasons other than for the conservation purposes as described in chapter 3. These include control of pest species, scientific research or facilitation of building developments. These interventions carry an associated disease risk to the focal species, sympatric wildlife, humans, pets or livestock (Cunningham, 1996; Kock, Woodford, & Rossiter, 2010; Woodford & Rossiter, 1993).

In conservation interventions, the potential impacts of disease on the focus species is a driver for voluntary and proactive decision making regarding risk assessment and risk mitigation. There is no such incentive for licence applicants such as pest control operators or building developers who will incur costs relating to wildlife protection actions which are not their primary concern. Wildlife legislation controls and licences some wildlife interventions. The issuing of a licence is a control point at which the

potential disease risk of the action can be assessed and if necessary conditions placed on the licences in attempt to mitigate risks identified.

There is very little literature regarding the use of licenses as a tool in wildlife management and those that do exist focus on the effectiveness of the licence conditions (Delahay et al., 2009; Prest, 1995; Stone, Jones, & Harris, 2013). Despite strong demand for evidence based policy making in conservation management (Pullin, Knight, Stone, & Charman, 2004; Sutherland, 2003) papers that describe the integration of evidence into the licensing processes have not been produced. The work presented in the current chapter aimed to contribute to addressing this gap. The lack of publications is likely to be due to the reluctance of legislators to invite criticism regarding the robustness of the procedure. The risk management actions that can be required will be limited by legal powers of the licence, financial and technical expertise of both decision makers and licence applicants, the amount of evidence available and powers of enforcement.

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4.4 Published paper

Assessment and Mitigation Process for Disease Risks Associated with Wildlife Management and Conservation Interventions.

M. Hartley and E. Gill

This paper describes the disease risk assessment procedure that is adopted for wildlife and conservation interventions controlled by wildlife legislation in England. A simple risk algorithm was developed that is used to identify and prioritise the procedures of most concern. The process provides a system that is intended to be practicable to implement, proportionate to the associated risks, and ensures that costs are not escalated so that the activity becomes unviable.

Introduction

Wildlife movements occur on a global scale with inherent risk of exposure of wildlife, livestock and humans to infectious agents. This paper describes the disease risk assessment procedure adopted for those wildlife and conservation interventions controlled by wildlife legislation in England. A simple risk algorithm has been developed which is used to identify and prioritise the procedures of most concern. The process provides a system which is intended to be practicable to implement, proportionate to the associated risks and ensures that costs are not escalated so that the activity became unviable.

Wildlife management and research activities often involve the capture, transportation or release of wildlife. This may be undertaken for a number of purposes including: scientific research, pest control, facilitating building developments and for species conservation. Wildlife movements occur on a global scale with inherent risk of exposure of wildlife, livestock and humans to infectious agents. Translocation of any animal is in fact the translocation of a biological package and, once released into a free-ranging system, animals are difficult, if not impossible, to retrieve (Bengis and

others 2002). Captive breeding and release programmes can potentially transfer pathogens into previously unexposed wild populations (Woodford and Rossiter, 1993). This may be a risk to sympatric wild species at the site. Movement or introduction of wildlife can also impact on the health status of livestock, companion animals and humans (Cunningham, 1996, Chipman and others 2008).
There are few enforceable regulations to protect against disease threats to or from wild animals. The conservation community guidelines are underused with 24% translocations having no disease screening and only 25% undertaking investigations into deaths of translocated animals (Dasak and others 2000).

There are several papers and advisory guidelines describing potential protocols to minimise disease transmission from wildlife translocations and re-introductions (Woodford and Rossister 1993, Cunningham 1996, Leighton 2002). However there are few describing pragmatic and cost-effective implementation of these guidelines and how legislation can be used to enforce these precautions.

In the UK, legislation such as the Wildlife & Countryside Act (1981), the Protection of Badgers Act (1992), The Conservation (Habitats Regulations (1994) and the Deer Act 1991 (as amended 2007) protects certain wildlife species from being taken, killed, kept and disturbed, and their habitat or home from being interfered with or destroyed. Within each Act, licences may be issued to allow otherwise prohibited activities for certain purposes which, depending on the legislation, may include: scientific research, protection of crops, livestock and foodstuffs, preserving public health and safety, conservation, damage to property and land, development and sale.

In England these licences are issued by Natural England, the statutory body responsible for conservation and wildlife management. Applications for licences received by Natural England are assessed by an appropriately qualified wildlife biologist (the Wildlife Advisor) and their issue is subject to certain criteria being met. It was recognised that some activities taken under licence had the potential to introduce diseases to free-living wildlife, livestock or humans or to spread infectious diseases to new areas and populations. It was therefore decided that consideration of these potential disease risks should be included as a component of the assessment of the licence application. Then, if it was considered appropriate, additional licence

conditions with the purpose of mitigating identified disease risks could be included on the licence or, if the procedure posed a significant risk which could not be managed, a licence would not be issued.

Materials and Methods

Consideration was given to the actions permitted under licence and the disease risks associated with them. The potential disease transmission pathways relevant to the licensed activities were identified together with transmission pathways that could be created or increased by the proposed procedures. Those that could occur through natural phenomena such as juvenile dispersal are excluded.

The procedures were classified into four categories which would result in one of five licensing outcomes, namely: no additional licence conditions, additional licence conditions imposed by a wildlife advisor, additional licence conditions imposed by a government wildlife veterinarian, a request for a qualitative veterinary risk assessment, and refusal of the licence. This is presented in a simplified form in the flow chart in figure 1. Due to the individual nature of many licences it was also recognised that communication and negotiation between the applicant, licensing authority and veterinarians to ensure appropriate and proportionate conditions is essential.

An established procedure for licence applications relating to the European badger *(Meles meles)*, as a component of mitigation measures for bovine tuberculosis, pre-dates the process outlined here (Defra-unpublished).

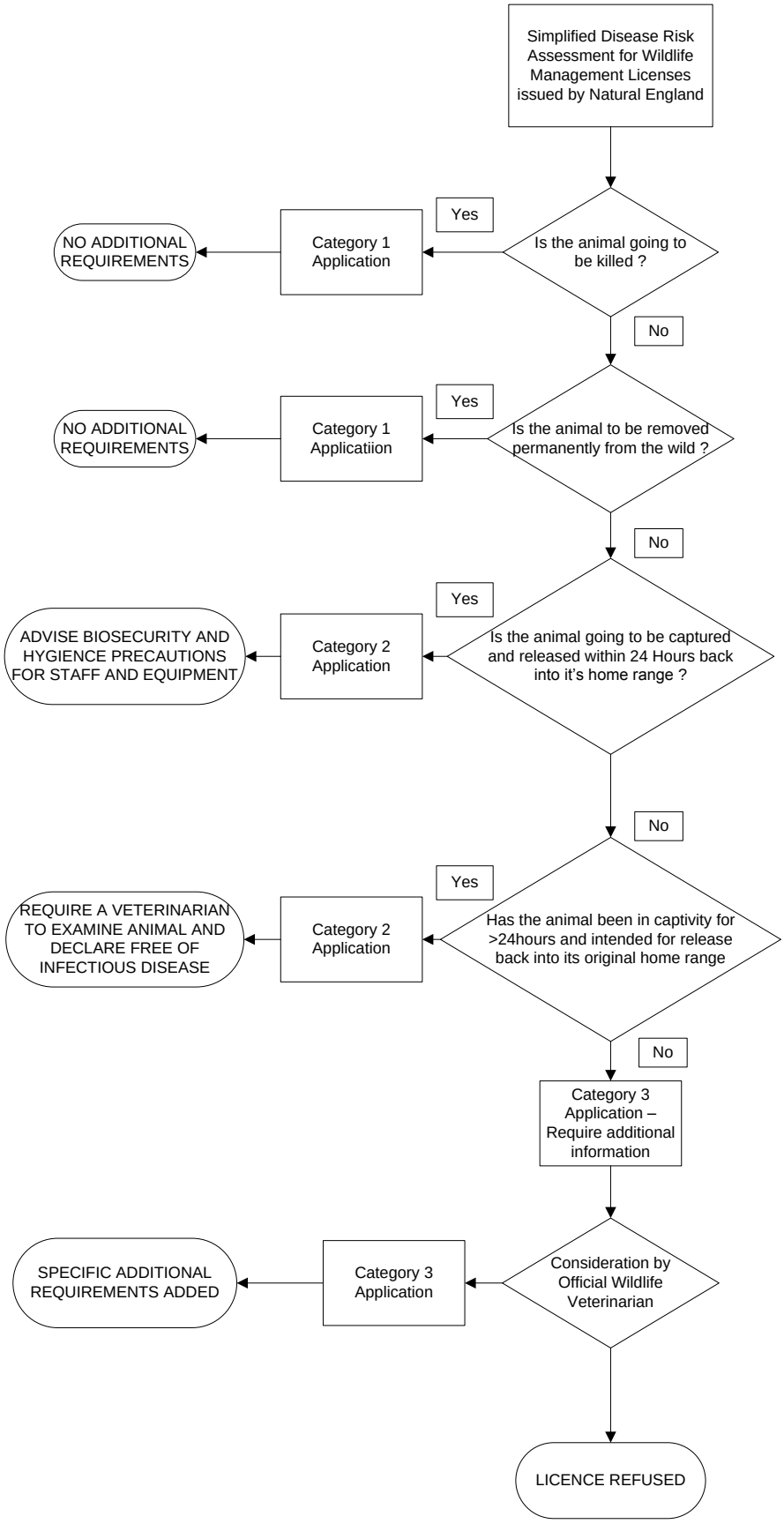

Figure 1 – Flow chart summarising decision making process.

Results

Some licensed procedures pose a negligible disease risk and therefore can be issued without veterinary consideration. This is a ‘Category 1’ licence. These are procedures that, for example, involve the permanent removal of animals from the wild through licensed killing (with appropriate carcase disposal) or taking animals into captivity where they will be isolated from free-ranging conspecifics. These animals will have no further contact with free-ranging wildlife. Also considered to pose a negligible disease risk was the disturbance or relocation of animals within their home range, and keeping or selling captive animals with no intention of release. In the above instances, animals permanently held in a captive facility are considered to either pose negligible risks to wildlife, livestock or members of the public or else risks are managed through alternative legislation.

The second disease risk category includes activities which involve the capture of wild animals with subsequent release back in to it’s original home range, following a brief period of captivity. This could include capture of wild animals for telemetry studies or biological sampling or the release of rehabilitated animals from a wildlife hospital. The disease risk associated with these interventions is related to the length of time in captivity and the exposure pathways for disease that could occur during the intervention. For example, wildlife captured for application of a telemetry device and released immediately would only be exposed to novel pathogens originating from the humans who handled the wild animal or the equipment used. However if the wild animal is to be captured and kept in captivity for a period of time then the potential exposure pathways increase. In these cases the wildlife advisor will add a number of specific licence conditions which aim to mitigate these risks. These are focused on hygiene and biosecurity measures or declaration from a veterinarian that the animal is free of clinical signs of infectious diseases. These additional conditions were previously agreed with government wildlife veterinarians and there is no requirement for further consultation. An example of a scenario for which the procedure would be assessed to be in Category 2 is provided below.

Procedure subject to Category 2 Licence

The Great Crested Newt (*Triturus cristatus*) is fully protected in the UK under both European and UK legislation. For example, where newts exist on a site that is to be developed, it is will nearly always be necessary for the developer to obtain a licence to disturb the animals or destroy their habitat. Such a licence will always include conditions to ensure that the newts are not harmed and that there is suitable compensation and mitigation for the animals and any losses of habitat they incur as a result of the proposed development. This often involves moving the newts to a safe and suitable habitat. This is usually with 1km of the original site. As newts naturally migrate over this distance the movement is considered 'low risk'. However, the licence would be issued with a requirement that biosecurity and hygiene measures should be applied to reduce the risk of the anthropogenic transmission of Chytridomycosis and Rana Virus.

The third category includes interventions regarded as potentially having a high risk of disease introduction. These will be referred to a government wildlife veterinarian for further assessment. They include applications to move an animal outside of its home range, the release of imported wildlife, or the movement of species for which there are particular concerns of disease such as pox virus in squirrels and chytridmycosis in amphibians.

When a proposed intervention has been assessed to be in this third, higher risk category, the applicant is asked to provide additional information on the proposed action, this may include: intended veterinary involvement, such as health examinations and quarantine procedures, biosecurity precautions and (if appropriate) post-mortem investigations. The application and supporting information is referred by the wildlife Advisor to the wildlife veterinarian who will undertake the following structured review process in order to define the most appropriate course of action.

The first second stage of the review is to consider and prioritise the diseases of concern. The potential negative impacts that disease introduced by translocated or released wildlife could have are summarised as: introduction of disease into wildlife populations at the site of release, introduction of disease into livestock at the site of release and introduction of disease into humans at the site of release.

Wildlife disease surveillance is undertaken by both government and non-governmental organisations within the UK. The results of this work are reported on an annual basis to the World Organisation for Animal Health (OIE). www.defra.gov.uk/vla/reports/rep_wildlife.htm

This evidence is used to identify those diseases endemic in wildlife in the UK. There is scarce information on geographical distribution of most endemic wildlife diseases in the UK and therefore negligible substantial scientific evidence to base restrictions on licences with the intention of controlling known endemic diseases. Exceptions to this exist for parapox virus in red squirrels, and chytridmycosis and rana virus in amphibians. Geographical distribution information is available for these diseases which have been implicated in population level impacts on wildlife populations. The UK government is currently undertaking research and mitigation programmes in relation to these diseases.

The priority diseases of concern are those which would have the greatest impact on wildlife populations, human health and the economy. This equates to exotic diseases with particular focus on notifiable diseases, however the UK is currently considered free of a number of significant pathogens with wildlife reservoirs such as *Trichinella sp., Echinococcus multilocularis* and tularaemia (Defra, 2007).

Having identified the potential exposure pathways and diseases of most concern in relation to the proposed licensed action, the wildlife veterinarian then considers practical and affordable mitigation measures which could be applied. In many cases these are simple generic precautions such as biosecurity and hygiene practices or clinical inspection by a veterinarian prior to release. Occasionally specific pathogen testing is requested. An example of a licence application assessed to be in Category 3 for which pathogen testing was requested is provided below.

Procedure subject to a Category 3 Licence

An application was received to translocate a pair of mute swans (*Cygnus olor*) from a lake, where they were attacking leisure users, to a waterfowl sanctuary. In this scenario it is important to ensure that the proposed intervention does not introduce disease to the waterfowl sanctuary. Therefore the wildlife veterinarian required that

the birds should be tested for high pathogenic avian influenza of the H5 and H7 subtypes prior to movement. These serotypes are notifiable diseases in the UK and require statutory disease control measures to be implemented when disease is identified. The birds were not tested for other serotypes of influenza virus as these are found routinely in waterfowl species and could be introduced to the sanctuary by natural movements of waterfowl.

There may be instances when the wildlife veterinarian decides that the risks to wildlife health associated with the proposed licensed action are too great and that there are no practical mitigation measures which would manage the risk adequately. In such a case the application would normally be refused. An example of a procedure which was refused a licence is provided below.

Procedure for which a licence was refused.

Chinese water deer (*Hydropotes inermis*) are a non-native deer species introduced into the East of England around 100 years ago. A request was received to move wild caught Chinese water deer from Norfolk to establish a captive herd in a deer park in the North West of England, an important dairy farming area..

In 2007, Bluetongue virus was diagnosed in the UK for the first time. The outbreak occurred in the East of England and the Midlands. Deer are known to be susceptible to Bluetongue virus but little work has been done on the epidemiology and pathology of the disease in this species.

It was decided that the translocation of these potentially infected deer to an uninfected area of the country with a high value livestock population was too great a risk and it was advised that a licence would not be issued.

A fourth disease risk category is used only in exceptional circumstances, primarily prior to licensing a formal re-introduction programme. Under these circumstances a full veterinary risk assessment, including risk management procedures, is requested. This must be undertaken by the applicants at their cost. This is then considered by the government wildlife veterinarian who advises whether all the potential disease risks have been identified and if they will be addressed by measures described. Any such project would be encouraged to have appropriately qualified veterinary supervision,

quarantine regimes, individual animal identification, pre and post release disease surveillance, necropsy procedures and medical records.

Once the wildlife advisor and veterinarian have agreed on appropriate licence conditions the requirements are communicated back to the applicant. Negotiation to ensure the licence conditions are appropriate and achievable is possible and advice is provided to ensure successful outcomes and cooperative collaboration. All the above should also comply with the International Union for Conservation of Nature and Natural Resources (IUCN) Guidelines for Re-introductions (1998). Once issued, the licence would also require that appropriate monitoring was carried out as specified in the IUCN Guidelines.
Any appeals to the above process would be considered by a review panel of senior officials from Natural England and Defra. An independent veterinary review may also be considered.

Discussion

This paper describes the disease risk assessment procedure adopted for those wildlife and conservation interventions controlled by UK wildlife legislation in England. It is recognised that this process does not address all potential risks in all scenarios but it is a structured approach to working within the boundaries of existing legislation and will be developed and modified as necessary to reflect increasing knowledge and experience.

The assessment procedure developed needed to be feasible to undertake with minimal additional resource requirements, straightforward to implement in a consistent manner and be based on sound scientific evidence. It was also recognised that the procedures undertaken under licence can be of benefit to wildlife populations and that any additional conditions added to licences to reduce disease risks needed to be practicable to implement, proportionate to the associated risks and that costs were not escalated so that the activity became unviable.

The simple risk algorithm which is used to identify and prioritise the procedures of most concern could be adapted by wildlife managers and veterinarians in other

governments, agencies and organisations and the concepts outlined modified as appropriate.

Acknowledgement

This work was completed as a component of the implementation of the England Wildlife Health Strategy.
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Chapter 5. The Use of Risk Analysis to Inform Wildlife Disease Control Policy. Qualitative Veterinary Risk Assessment of the Role of Wild Deer in the Likelihood of Incursion and the Impact on Effective Disease Control of Selected Exotic Notifiable Diseases in Great Britain.

5.1 Authorship Statement.

Dr Faye Voller managed the literature searches and data extraction which form the basis of the paper. Dr Tess Murray developed the risk maps and undertook data analysis. Dr Helen Roberts provided domestic animal risk policy advice and reviewed the work. The construction of the risk scenario trees, development of the risk assessment and the management conclusions reached were undertaken by myself.

5.2 Introduction to published paper

The paper in this chapter (Hartley, Voller, Murray & Roberts, 2013) was commissioned by the Department of Environment, Food and Rural Affairs during the triple notifiable disease outbreaks of 2007. The role of deer in the epidemiology of Foot and Mouth Disease and Blue Tongue Virus is poorly understood. This lack of knowledge and data compromised disease control decision making and hindered prioritisation of scarce resources and expertise and so this disease risk assessment was commissioned during the official review investigations after the outbreaks.

The majority of diseases considered to be of most importance to human and livestock health and the economy, infect multiple hosts (Gortazar et al., 2015; Haydon, Cleaveland, Taylor, & Laurenson, 2002). Wildlife may be reservoirs, vectors or casualties of these diseases (Gortazar et al., 2015) (Artois, Delahay, Guberti, & Cheeseman, 2001). Disease emergence in wildlife (e.g. West Nile Virus, Chronic Wasting Disease) (Bengis et al., 2004; Williams, Yuill, Artois, Fischer, & Haigh, 2002) and persistence in endemic diseases such as tuberculosis have led to recognition of

the challenges of disease control in wildlife (Gortazar et al., 2015; Gortázar, Ferroglio, Höfle, Frölich, & Vicente, 2007).

The control of disease in wildlife requires multifaceted approaches including preventative measures, population control and vaccination in order to reduce pathogen transmission between wildlife and domestic animals and humans (Gortazar et al., 2015). This requires identification and understanding of reservoirs of infection, population size, susceptibility and pathogenicity (Artois et al., 2001; Haydon et al., 2002). In most circumstances we have a poor understanding of the epidemiology of wildlife diseases (Haydon et al., 2002) and very little understanding of the consequences of interventions (Gortázar et al., 2007). In addition, the behaviour and ecology of the species and the impact of these factors on disease epidemiology must, but are rarely, considered. The behaviour and ecology of a species significantly impact on the risk outcomes and the paper presented in this chapter highlights the importance of including these factors in the analysis.

For most wildlife diseases there is no strong justification for intervention in terms of public or animal health or conservation, or if a justification does exist there are no suitable and cost-efficient disease control tools available (Gilmour & Munro, 1991; Gortazar et al., 2015). Taking no action is controversial and necessitates justification. Therefore, the production of a risk assessment such as the paper in this chapter (Hartley et al, 2013) allows risk managers to communicate and justify decisions in a structured and transparent way as was done with this paper.

Techniques such as disease prevalence surveys, population modelling and experimental infection studies have been used alongside risk analysis to assess impacts and risks caused by individual named diseases in specific scenarios. Examples include tuberculosis in badgers and cattle in the UK (Delahay, Cheeseman, & Clifton-Hadley, 2001; Garnett, Delahay, & Roper, 2002) and foot and mouth disease in buffalo (Jori et al., 2009; Sutmoller, Thomson, Hargreaves, Foggin, & Anderson, 2000). These studies are commissioned when a disease threat has been identified due to a change in distribution or prevalence or during an actual disease outbreak when animals are already infected. These have contributed to wildlife disease control policy making resulting in interventions in limited circumstances.

There are very few risk assessments which are commissioned by policy makers pre-empting wildlife disease outbreaks in order to pre-determine policy despite this being recognised as important (Bar-Yaacov, 2008). Hartley and colleagues developed risk assessments in order to develop policy for notifiable disease control in wild boar (Hartley, 2010) and, as discussed in this chapter, five species of deer in the UK (Hartley et al, 2013). These complex assessments expanded the approach to risk analysis by considering multiple diseases in multiple species but remained consistent with accepted and recognised standards and formats of risk assessment. The data in this chapter was presented using scenario trees and risk tables as described by MacDiarmid & Pharo (2003). The need for these more complex assessments, expanding on the single scenario assessments, which include uncertainty estimations, multiple exposure pathways and comparison of equal risk in management frameworks has been identified as a required development (Eduljee, 2000). This paper delivers these developments.

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5.4 Published paper

Qualitative Veterinary Risk Assessment of the Role of Wild Deer in the Likelihood of Incursion and the Impact on Effective Disease Control of Selected Exotic Notifiable Diseases in Great Britain.

M Hartley, F Voller, T Murray & H Roberts

Abstract

A qualitative risk assessment was undertaken to analyse the likelihood of the incursion of selected exotic infectious disease into deer populations in GB and the potential impacts these animals could have on effective disease control. In order to identify the exposure pathways, it was necessary to consider not only the epidemiology of the pathogens but also to understand the impact of the ecology and behaviour of wild deer on disease transmission. It was concluded that the greatest risk of exotic disease incursion into wild deer in GB was disease incursions occurring in domestic ruminants first then transmitting to wild deer. The qualitative risk assessment considered geographic spread and habitats of wild deer and the susceptibility of wild deer to notifiable exotic diseases of domestic ruminants. Data of some diseases in some deer species is limited and the overall assessment of impact varied between diseases and deer species; Red deer pose the highest risk of the species reviewed. The overall risk assessment of low is primarily influenced by the low risk of incursion of exotic diseases generally into the UK.

Introduction

Six species of deer are free-living in the wild in the UK: Roe (*Capreolus capreolus*) and Red (*Cervus elephas*) are native to Great Britain; the Fallow deer (*Dama dama*) was introduced in Norman times (c. 11th century); the Sika (*Cervus nippon*), Muntjac (*Muntiacus reevesi*) and Chinese water deer (*Hydropotes inermis*) are relatively recent

introductions being released from deer parks, accidentally and deliberately, in the twentieth century.

Deer species, as with other wildlife are susceptible to a wide range of pathogens which may impact on human health and livestock health (Simpson, 2002; Bourne *et al*., 2007; Ruiz-Fons, 2008b; Hartley, 2010). Deer, as ruminants, may act as incidental 'spill-over' hosts, disease vectors or true reservoirs of diseases which affect domestic ruminants such as cattle. Deer may therefore influence the epidemiology of the disease and the effectiveness of disease control (Böhm *et al*., 2007).

There are a number of notifiable exotic diseases that the UK is considered to be free of infection in both domestic and wild ruminants. Deer, as ruminants, are potentially susceptible to diseases of other ruminants such as cattle and sheep and could potentially play an important role in the spread of disease. A single confirmed case of these diseases would result in an official outbreak response, disease control measures and trade restrictions resulting in negative social and economic impacts.

Information on the susceptibility and epidemiology of infectious notifiable diseases in deer in England is dated, fragmented and incomplete (Defra 2009b). In addition, there have been few studies on the influence of behavioural ecology and population density of deer on disease transmission (Defra 2009b). This is especially important as deer populations in England have increased significantly over the last 40 years and continue to do so (Defra 2010).

Previously, the potential role of deer in outbreaks of notifiable diseases in England had been considered at the time of an outbreak and based on expert opinion, not allowing knowledge gaps to be addressed proactively, surveillance to be undertaken or mitigation measures to be implemented. The England Wildlife Health Strategy (Defra 2009b) identified that wildlife disease contingency plans should be produced to address the unique challenges of disease control in free-living wildlife. This risk assessment collates current understanding into a structured format to enable assessment of potential risks and uncertainties therefore allowing evidence-based decision-making and policy development for disease control.

Materials and Methods

This qualitative risk assessment examines the likelihood of incursion and the potential impacts of infection of the six species of deer found in Great Britain with 16 diseases of ruminants that are notifiable in the UK through legislation.

This complex assessment requires modification of standard risk assessment approaches as these are designed to focus on one species and one hazard. The methodology utilised was developed for the specific requirements of the policy-making process within the Department of Environment, Food and Rural Affairs. This process has been endorsed through a process of peer review, which includes publication (Hartley 2010). It is closely aligned with the OIE Risk Assessment Framework (OIE 2004). Further examples can be viewed at www.defra.gov.uk/animaldiseases/monitoring/risk-assessments/. The risk assessment is composed of four components as shown in Fig. 1.

Fig. 1 Risk analysis process used in this work based on OIE methodology (OIE 2004)

Hazard identification determines the risks, which are to be assessed. In this case, the notifiable diseases which deer are susceptible to and therefore could pay a role in the epidemiology of an outbreak. Once the hazards have been determined, the three components of the risk assessment can be undertaken. The release assessment describes the biological pathways for the release of the hazard, which in this study, as England is currently free of the notifiable diseases, are the pathways of excursion into ruminants (either domestic or wild) in England. The exposure assessment is the description of biological pathways necessary for exposure of the target population, in this study, six species of wild deer, to the hazards released and estimation of its probability. The consequence assessment is the description of relationships between exposures to hazards and consequences of those exposures (biological and

economic). Finally, the risk estimation is the integration of results from previous three steps to produce overall measures of the current risk associated with the hazards. The risk assessment uses the risk terminology as shown in Table 1.

Table 1 Risk terminology used in this assessment

Term	Definition
Likelihood	Probability; the state or fact of being likely
Likely	Probable; such as well might happen or be true; to be reasonably expected
Negligible	So rare that it does not merit to be considered;
Very low	Very rare but cannot be excluded;
Low	Rare but does occur;
Medium	Occurs regularly;
High	Occurs very often.

Uncertainty is categorised as shown in Table 2.

Table 2 Uncertainty categories used in this assessment

Low	Solid and complete data available; strong evidence provided in multiple references; authors report similar conclusions;
Medium	Some but no complete data available; evidence provided in small number of references; authors report conclusions that vary from one another;
High	Scarce or no data available; evidence not provided in references but rather in unpublished reports or based on observations, or personal communication; authors report conclusions that vary considerably between them.

Hazard Identification

The notifiable disease of ruminants in the UK are shown in Table 3. From this list, the hazards for this risk assessment must be determined by identifying those relevant to the six species of deer in England.

Table 3 The exotic diseases of ruminants notifiable in the UK are:

Notifiable Disease	Main species affected	Occurred last in Great Britain
Bluetongue	All ruminants and camelids	2011
Brucellosis (*Brucella abortus*)	Cattle	2004
Brucellosis (*Brucella melitensis*)	Sheep and goats	Never
Contagious agalactia	Sheep and goats	Never
Contagious bovine pleuro-pneumonia	Cattle	1898
Contagious epididymitis (*Brucella ovis*)	Sheep and goats	Never
Enzootic bovine leukosis	Cattle	1996
Epizootic haemorrhagic virus disease	Deer	Never
Foot and Mouth Disease	Cattle, sheep, pigs and other cloven hoofed animals	2007
Goat pox	Goats	Never
Lumpy skin disease	Cattle	Never
Pest des petits ruminants	Sheep and goats	Never
Rift valley fever	Cattle, sheep and goats	Never
Sheep pox	Sheep	1866
Vesicular stomatitis	Cattle, pigs and horses	Never
Warble fly	Cattle (also deer and horses)	1990

Anthrax, rabies and rinderpest have been excluded from the list of hazards: anthrax and rabies can be carried and transmitted by all mammals and therefore is outside the focus of this paper and rinderpest has been globally eradicated and is therefore not considered a potential hazard.

Bluetongue virus is capable of infecting most ruminant species, in which it may cause clinical or subclinical disease. The disease has a global distribution across temperate and subtropical latitudes, but has recently been expanding, particularly across northern Europe. There are 24 (possibly 25) serotypes, which confer little or no cross-protection and which cause varying disease across species. The disease is carried by Culicoides midges and therefore outbreaks occur during the season when midge activity is at a peak. Virus has been isolated from experimentally infected deer as well as naturally infected deer.

It is generally accepted that BTV is able to infect and replicate in all species of ruminant, domestic and wild, (Jessup, 1985; House *et al*., 1982; Stallknecht & Howerth, 2004; MacLachlan, 2004). For wild ruminants, clinical disease seems to be common only in North America where mortality and morbidity have been documented in White -tailed deer *(Odocoileus virginianus),* Mule deer *(0. hemionus)* and Elk *(*the American subspecies of Red deer, *Cervus elaphus*) with White -tailed deer the most severely affected (Stallknecht & Howerth 2004, Hourrigan & Klingsporn, 1975, Hoff *et al*. 1974; Sohn & Yuill, 1991, Murray & Trainer, 1970).

BTV RNA can be detected in red deer following infection although is often low, transient and asymptomatic (Lopez-Olvera *et al*., 2010). Red deer normally become infected and viraemic whereas the Roe deer merely mounted an immune response and seroconverted (Linden *et al*. 2010). There is very little information available on BTV infection in other species of deer; clinical disease has been reported in captive Muntjac in North America (Hoff *et al*., 1973) and antibodies, but no clinical disease has been demonstrated in Sika deer (Corn *et al*., 1990).

Bluetongue became widespread in farmed livestock in Northern Europe following an initial outbreak in 2006. Over this time the number of red deer testing seropositive for BTV-8 increased to 50% but there was not affect on mortality levels (Linden et al 2008, 2010). It is unknown whether Red deer can act as reservoirs. Prevalence of seropositivity over same time and geographic area was lower in Roe deer (2.6%; Linden *et al*., 2010). In the UK, however 142 wild deer samples, in areas where BTV-8 was circulating in 2007 tested negative for antibodies (Chris Oura, 2010 personal communication).

Brucella abortus has been detected in a naturally and experimentally infected fallow, red, sika, mule, white-tailed and roe deer, moose, reindeer and caribou. It has been concluded that the epidemiology of the disease is similar to that in cattle and the disease is known to be transmitted between deer and cattle (Etter & Drew, 2006). Naturally occurring *B*. *ovis* infection disease has been reported in farmed Red deer in New Zealand (Bailey, 1997). A serosurvey of Roe deer for *B. ovis* in the Italian Alps, an area with endemically infected sheep found no evidence of infection (Gaffuri *et al*., 2006). During the *Brucella* spp. eradication programme in GB both blood samples and

genital tracts of deer were examined for *Brucella* infection. Over a ten year period from 1964-1974, the organism was never detected by serological examination in 670 animals of six species or in surveys of genital tracts, of pregnant animals (McDiarmid & Matthews, 1974).

Antibodies to the aetiological agent *Mycoplasma agalactiae,* have been reported in Roe and Red deer (CSFPH, 2003).

Only four species of cervids: mule deer *(Odocoileus hemionus)*, white-tailed deer *(O. virginianus),* elk *(Cervus Canadensis)* and moose *(Alces alces)*, are known to be susceptible to Chronic Wasting Disease (CWD) (other than via intracerebral inoculation). Many other species have been in-contact with infected animals or resided on infected premises have not developed the disease, including cattle. Chronic Wasting Disease has only been reported in North America and farmed deer in South Korea. No Transmissible Spongiform Encephalopathies (TSEs, including CWD) positive results were found in 13,000 samples taken between 2006-2010 of several deer species from 21 EU Member States (including UK) and Norway (EFSA, 2010). Smaller studies including roe, fallow, sika and muntjac deer showed no positive results for TSEs (SEAC, 2005). Fallow deer are susceptible via the intracerebral route (Hamir *et al*. 2011) and like elk, European red deer are experimentally susceptible (Martin *et al*. 2009).

Enzootic Bovine Leukosis is present in some EU Member States, where countries may be considered free or regionalised for freedom. There is no evidence for cervids being affected by EBL naturally (Frolich & Flach, 1998; Muller *et al*. 1997, Dedek *et al*. 1987) although antibodies can be detected following experimental infection (OIE 2008a). The virus (Bovine Leukosis virus) causes subclinical and clinical disease in adult cattle; the latter can develop lymphosarcomas. Infection has been detected in buffaloes, sheep and capybaras and many animals show a persistent antibody response after experimental infection (OIE, 2011). There are very limited studies on the epidemiology of Enzootic Bovine Leukosis in deer species however those completed found that there

was no evidence of infection in Roe, Red or Fallow deer even in endemically infected areas (Muller *et al*., 1997; Lemesh *et al*., 1988; Dedek *et al*., 1987).

Epizootic Haemorrhagic Disease virus is similar to BTV and is also transmitted by *Culicoides* midges. It occurs most commonly in North America, particularly the USA, although strains do occur in other parts of the World. It can potentially infect most wild and domestic ruminants however clinical disease has only been identified in White-tailed and Mule deer. The former species is highly susceptible with the disease manifesting as sporadic, locally severe mortality with a number of epizootics causing population level impacts, Mule deer are normally free of clinical signs but do become seropositive (Hoff & Trainer, 1978). Red, Fallow and Roe deer have been found to be seropositive (OIE, 2009). Red, Fallow, Roe and Muntjac deer experimentally infected with EHD virus produce a low level of viraemia but no clinical disease indicating some susceptibility (Gibbs & Lawman 1977). Viruses from the EHD group have been found in cattle throughout the world including Africa, Australia Japan and Israel, yet outside of North America disease has not been associated with disease in deer and in USA serotypes in cattle are different to those identified in deer species (Sohn & Yuill, 1991). It is important to note though that diseases including the similar BTV can jump and *Culicoides* midges are present in GB.

A least five of the six deer species resident in GB (Chinese water deer not tested) are susceptible to FMDV following exposure to infected cattle, in an experimental setting and Red deer can also become carriers (Gibbs *et al*., 1975; Forman & Gibbs, 1974). Clinical disease is severe in Roe and Muntjac, less severe in Sika and usually subclinical in Fallow and Red. (Gibbs *et al*.,1975; Forman & Gibbs, 1974). Viraemia titre in FMD infected Red, Fallow, Sika, Muntjac and Roe deer is similar to that of sheep and cattle (Forman *et al*. 1974; Gibbs *et al*. 1975). As with livestock there is a risk of aerosol transmission from deer especially with Fallow and Sika deer who can carry the virus in the pharynx for at least four weeks (Forman et al. 1974; Gibbs *et al*. 1975). Elk do not present obvious clinical signs and only very rarely transmit to other animals (Ryhan *et al*. 2008).

Internationally, during FMD outbreaks in the last six decades ‘spillover’ from infected livestock to free ranging deer or ‘spillback’ into deer has not been reported (Mouchantat

et al., 2005). In the GB outbreak in 1967-8 there was no evidence of deer involvement in the outbreak (Thrushfield & Fletcher, 2002). In 2001, despite reports of wild deer showing clinical signs of FMD all 484 samples from wild and farmed deer considered to be exposed to or at risk of FMDV tested negative (Elbers *et al*., 2003). During the 2001 outbreak in the Netherlands no wild deer sampled were positive for FMD from Netherlands or roe deer from a neighbouring area of Germany (Mouchantat *et al*., 2005).

There is a lack of evidence to determine if Lumpy Skin Disease or Sheep pox affects Cervids. Of the limited studies conducted no antibodies were detected in Red, Roe and Fallow deer samples (N=164) in Germany, for sheep and goat poxvirus (Frolich *et al*., 2006) however the diseases are not endemic in Europe. Goat pox has been transmitted experimentally to a single reindeer (*Rangifer tarandus*; Bakos & Brag, 1957).

There are no reports of natural infection of Pest des Petits Ruminants (PPR) in any species of deer. Experimental infection of White-tailed deer with the PPR virus did however result in clinical or subclinical infection (Hamdy and Dardiri, 1976).

Rift Valley Fever is a disease of domestic ruminants which also affects humans (OIE 2008b), and there is little evidence to suggest cervids would not be infected as the countries where the disease is endemic have no farmed deer or deer outside zoos. It is transmitted by *Aedes* spp mosquitoes and epidemics are associated with heavy rainfall and concurrent increase in vector populations. The disease causes mass abortion storms in small ruminants and cattle and camellids are also affected.

Vesicular Stomatitis is a disease restricted to the Americas, and found in cattle, horses and small ruminants. It is believed to be transmitted by vectors, although the evidence is not definitive. The disease is important for its differential diagnosis with Foot and Mouth Disease. Seroprevalence for vesicular stomatitis has been reported in White tailed deer (Fletcher *et al*.,1991; Stallknecht & Erickson, 1986), Mule deer and Elk (Webb *et al*., 1987). Experimental infection in deer (species unknown although the study was conducted in the USA) resulted in fever, vesicles and mouth lesions but viraemia was short (Karstad & Hanson, 1957).

Tarry (1981) surveyed warble fly (*Hypoderma* spp.) larvae from deer and horses during the warble fly eradication scheme in Britain. There was no evidence of cross-infestation between cow and deer warble species. *Hypoderma actaeon* is a parasite of Red deer in Europe and strictly host-specific (Perez *et al*., 1995). *Hypoderma diana* unlike other Hypoderma species, is adapted to several hosts, although Roe deer is the main host (Martinez-Moreno *et al*., 1997). Severe infestation with *H. diana* can negatively affect the condition of Red deer (Yeruham *et al*.,1994) and can occur at high prevalence (Martinez-Gomez *et al*., 1990). The bovid specific *Hypoderma bovis* appears not transmit to deer species.

Due to the lack of evidence that Cervidae are susceptible to Contagious Bovine Pleuropneumonia, Lumpy Skin Disease, Sheep pox, Goat pox and Rift Valley Fever these diseases are excluded from the list of hazards considered in the risk assessment. There is some although, very limited evidence that PPR causes diseases in deer and therefore it has also been excluded. It is possible that deer are susceptible to these diseases however the lack of evidence means they cannot be considered further in the context of this risk assessment.

The following diseases are considered as potential hazards suitable for risk assessment:
Bluetongue, Brucellosis, Chronic Wasting Disease, Contagious agalactoa, Enzootic Bovine Leukosis, Epizootic Haemorrhagic Disease, Foot and Mouth Disease, Vesicular Stomatitis, Warble Fly

Release Assessment

In this risk assessment, the release assessment describes the risk of incursion of notifiable diseases into susceptible ruminants in England. The hazards identified could be released into England via the routes shown in Table 4 (Roberts et al. 2011).

Table 4 Release Assessment is a function of transmission route, presence of disease in country of origin, level of legal trade in risk product, mitigation in country of origin and any illegal pathways. Adapted from RPV Project, Roberts et al. (2011) and (Tamguney et al. 2009)

Route of release	Trade in Livestock (excludes horses)	Trade in Meat and other products of animal origin	Trade in Germplasm	Livestock transport vehicles/fomites from abroad	Trade in Equidae	Waste from Retail/Food Processing	Contact between livestock & competent insect vectors in GB	Illegal imports	Contact between wild deer and competent insect vectors	Release Assessment Risk. *
Bluetongue	Yes	X	Yes	Yes	X	X	Yes	Yes	Yes	Low
Brucellosis (*Brucella abortus, B. melitensis, B. ovis*)	Yes	X	Yes	Yes	X	X	X	X	X	Low
Contagious agalactia	Yes	X	X	Yes	X	Yes	X	Yes	X	Low
Enzootic bovine leukosis	Yes	X	X	Yes	X	X	X	X	X	Low
Epizootic haemorrhagic virus disease	Yes	X	X	X	X	X	Yes	X	Yes	Negligible
Foot and Mouth Disease	Yes	Yes	Yes	Yes	X	Yes	X	Yes	X	Low
Vesicular Stomatitis	Yes	Yes	X	Yes	Yes	Yes	X	Yes	X	Negligible
Warblefly	Yes	X	X	X	X	X	X	X	X	Very Low
Chronic Wasting Disease	Yes	X	X	Yes	X	X	X	X	X	Negligible

The risk of exotic disease incursion into Great Britain is reduced by a series of measures enforced by European or national legislation. These include a requirement for animal owners and veterinarians to report suspicion of disease to official veterinarians for further investigation.

The likelihood of the introduction of the notifiable diseases listed in hazard identification into the UK would depend on the prevalence of notifiable disease in the country of origin (i.e., in wildlife or domestic animal population, or both) and therefore the potential prevalence of notifiable disease in animals travelling to the UK combined with compliance with risk reduction measures in place.

Import restrictions on the hazards identified include the requirement for health certificates to accompany animals documenting regional freedom from disease. In the event of an increase in risk identified in a consigning country, risk-based post import checks may be carried out at the premises of origin in GB. A contingency plan for dealing with exotic notifiable diseases is also in place (Defra 2009a). The risk of importation of CWD-, EHD- and VS-infected animals is mitigated through the restriction of import of livestock from USA or livestock or meat from South Korea.

The import measures, in conjunction with farm biosecurity and disease surveillance, protect the GB livestock and wildlife populations from exotic diseases. Of particular interest are imports of live deer. In 2010, 245 live cervids were imported into Great Britain of which 237 were reindeer (R. tarandus). All were species, which do not live in the wild in GB and were imported from Finland, Germany, Netherlands, Sweden and Switzerland (data from TRACES). For all routes except vector-borne diseases, it is likely that disease would be detected in livestock prior to detection in wild deer. Vector-borne infection could be introduced into wild deer through biting by infected vectors carried to Great Britain by wind. In this scenario, exposure risk will depend on the density of both livestock and wild deer but it is presumed, for the purposes of this risk assessment, that the vector does not favour one susceptible ruminant species above another.

Exposure Assessment

The exposure assessment examines the biological pathways that the six species of deer in England could become infected with the diseases identified in the hazard identification process. These diseases are those, which evidence suggests, these deer species are susceptible to and therefore could play a role in the epidemiology of an outbreak. The exposure assessment is summarised in Table 5.

Table 5 Table showing the exposure assessment for each disease in each species of deer

Disease	Species of Deer	Likelihood of deer species being susceptible to infection.	Likelihood of deer species being infected in field outbreaks	Likelihood that infected deer would transmit disease to livestock	Likelihood that infected livestock would transmit disease to deer	Overall Assessment of impact.
Bluetongue	Red	High	Low	Low	Medium	Medium
	Fallow	High	Low	Very Low	Low	Very Low
	Sika	High	Very Low	Very Low	Low	Very Low
	Roe	High	Very Low	Very Low	Low	Very Low
	Muntjac	High	–	–	–	–
	Chinese Water	High	–	–	–	–
Brucellosis	Red	Medium	Medium	Medium	Medium	Medium
	Fallow	–	Negligible	–	–	Negligible
	Sika	–	Negligible	–	–	–
	Roe	Low	Very Low	Very Low	Negligible	Negligible
	Muntjac	–	–	–	–	–
	Chinese Water	–	–	–	–	–
Contagious agalactia	Red	Low	Very Low	Very Low	Very Low	Very Low
	Fallow	–	–	–	–	–
	Sika	–	–	–	–	–
	Roe	Low	Very Low	Very Low	Very Low	Very Low
	Muntjac	–	–	–	–	–
	Chinese Water	–	–	–	–	–
Warble Fly	Red	High	High	Negligible	Negligible	Negligible
	Fallow	–	–	–	Negligible	Negligible
	Sika-	–	–	–	Negligible	Negligible
	Roe	High	High	Low	Very Low	Very Low
	Muntjac	–	–	–	Negligible	Negligible
	Chinese Water	–	–	–	Negligible	Negligible
Chronic Wasting Disease	Red	High	High	Negligible	Negligible	Negligible
	Fallow	Low	Very Low	Negligible	Negligible	Negligible
	Sika	–	Very Low	Negligible	Negligible	Negligible
	Roe	–	Very Low	Negligible	Negligible	Negligible
	Muntjac	–	Very Low	Negligible	Negligible	Negligible
	Chinese Water	–	–	Negligible	Negligible	Negligible

Enzootic Bovine Leukosis	Red	Negligible	Negligible	Negligible	Negligible	Negligible
	Fallow	Negligible	Negligible	Negligible	Negligible	Negligible
	Sika	–	–	–	–	–
	Roe	Negligible	Negligible	Negligible	Negligible	Negligible
	Muntjac	–	–	–	–	–
	Chinese Water	Negligible	Negligible	Negligible	Negligible	Negligible
Epizootic Haemorrhagic Disease	Red	Low	Very Low	Very Low	Negligible	Very Low
	Fallow	Low	Very Low	Very Low	Negligible	Very Low
	Sika	–	–	–	–	–
	Roe	Low	Very Low	Very Low	Negligible	Very Low
	Muntjac	Low	Very Low	Negligible	Negligible	Negligible
	Chinese Water	–	–	–	–	–
Foot and Mouth Disease	Red	High	Very Low	Very Low	Very Low	Very Low
	Fallow	High	Very Low	Very Low	Very Low	Very Low
	Sika	High	Very Low	Negligible	Negligible	Negligible
	Roe	High	Very Low	Very Low	Very Low	Very Low
	Muntjac	High	Very Low	Negligible	Negligible	Negligible
	Chinese Water	–	–	–	–	–
Vesicular Stomatitis	Red	Low	Low	Low	Medium	Low
	Fallow	–	–	–	–	–
	Sika	–	–	–	–	–
	Roe	–	–	–	–	–
	Muntjac	–	–	–	–	–
	Chinese Water	–	–	–	–	–

It must be remembered however that common susceptibility to a disease does not necessarily equate to shared infection. The existence of a pathogen in either wild deer or domestic ruminants is irrelevant to establishment of the disease in the other if the two populations do not interact; directly or indirectly. If populations do interact, pathogen establishment may be enhanced by the presence of an increased number of available hosts. For co-infection in both species to occur and for the epidemiology of the disease to be affected by this inter-species transmission, there must also be intra-species transmission so that two reservoirs of disease are established. Infection of single deer with disease is not significant; if the infected animal subsequently dies before transmitting the disease to another susceptible host, be it a domestic ruminant or another deer.

The potential routes of exposure of deer to the hazards are direct transmission such as airborne, direct contact with blood or body fluids and sexually transmitted routes and indirect transmission such as fomite (i.e., pathogen is transmitted on an object, including car tyres or dirt), vector borne, through an intermediate host and iatrogenic. Each hazard was individually reviewed to identify potential routes of transmission into wild deer. Experimental and natural transmission studies have provided disease-specific evidence for exposure risks.

As Bluetongue is primarily transmitted via insect vectors, all deer species are potentially at risk. In the event of an outbreak deer species, which share habitats with domestic livestock, are at greater risk due to the potential for an increased number of infected vectors in those areas.

Epizootic haemorrhagic disease is transmitted by Culicoides midges is primarily a disease of deer, although cattle may be affected (CFSPH 2006; Temizel et al. 2009). It is primarily found in the USA; strict import restrictions are in place to reduce the risk of this and other hazards and unlike Culicoides carrying Bluetongue on the near continent there is no risk of windborne spread to GB from USA.

Brucella spp. can be transmitted between deer and livestock via ingestion of contaminated feed and contact with environmental contamination (Ridler et al. 2000) although deer are far more likely to be at risk from cattle rather than the other way round (McDiarmid and Matthews 1974).

Due to transmission methods contagious agalactia and enzootic bovine leukosis are only a risk to those deer sharing pasture with infected domestic livestock.

Foot and mouth disease transmission can occur via direct contact, fomites and windborne spread (Defra 2009a), therefore all deer are potentially at risk although those closer to domestic livestock are at great risk. From experimental work, all GB deer species (including non-native, excluding Chinese water deer—not tested) can potentially transmit the virus intraspecifically and to cattle and sheep. Fallow, sika and some red deer can also become carriers (Gibbs et al. 1975; Forman and Gibbs 1974) meaning that FMD could circulate within wild deer populations and then back to livestock (Forman et al. 1974). Transmission through indirect contact such as oral transmission via shared grazing land is considered to be highly unlikely, particularly for sheep because the infective dose required via this route is high (Thrusfield and Fletcher 2002; Ward et al. (2007).

Intra-species transmission of vesicular stomatitis virus could occur via blood feeding insects. It is thought that in North America at least, deer may be epizootic hosts and

serve as a source of infection for insect vectors (Webb et al. 1987). This hazard is primarily found in the USA and strict import restrictions are in place to reduce the risk of importation and there is no risk of windborne spread of insects to GB from USA.

As direct contact is needed and deer appear not to be susceptible to H. bovis the risk of transmission of Warble Fly between deer and livestock is negligible. There has been reported however infestation of nonspecific hosts including sheep with H. diana which have been in contact with roe deer (Dempsey 1983).

Chronic wasting disease exhibits efficient horizontal transmission and deer can be infected orally and from contaminated environments although it is not clear how and when infective prions are shed. Prions have been demonstrated to be shed from blood, urine, saliva, antler velvet and tissues of symptomatic deer in late stage disease and by both asymptomatic and symptomatic deer in faeces (Tamguney et al. 2009). Livestock appear not to be susceptible to CWD, except via intracerebral injection (Hammir et al. 2011) and therefore the only risk would be to other deer species.

Geographic location

The risk of both direct and indirect disease transmission will be influenced by the geographic location of wild deer and livestock with a greater risk of transmission in areas of both high livestock density and high deer density. The range of all GB deer species is expanding.

Chinese Water deer occur patchily, in south-east England. The range is increasing (2% per year) although the population is small (1500 in 2005; Ward, 2005).

Muntjac deer (population - 52,000) are primarily in Eastern and Southern England with smaller populations elsewhere in England (Chapman, 2008). The population and range (8.2% per year) of this species is increasing (Ward, 2005).

Roe deer are present throughout much of GB; it is estimated that Roe deer will occupy 79% of all 10km squares in mainland Britain by 2015 (Ward, 2005; Hewison & Staines., 2008; NBN, 2011). A population of between 500,000 and 600,000 has been estimated,

however given the amount of available habitat the population could grow to one million (The Deer Initiative, 2011). Fewer Roe deer are found in Kent, Wales and a band of England between Leicester and Blackpool (NBN, 2011).

Red deer have a disjunct distribution; the main concentrations in the Scottish Highlands and Islands, South-West Scotland and South-West England (Staines *et al*., 2008). The Scottish population is an estimated 300,000 animals (The Deer Initiative, 2011).

Sika deer population is largest in Scotland (approximately 10,000 animals). English populations exist in the New Forest, Dorset/Devon and Forest of Bowland (Putman, 2008). The population is increasing (5.3% per year; Ward, 2005).

Fallow deer (population - 100,000) is primarily in England in lower lying areas (fewer in Peak District, Lake District, mid-Wales) with more scattered populations in Scotland and Wales (The Deer Initiative, 2011). The range of Fallow deer increased to a lesser extent than most other deer species (1.8% per year; Ward, 2005).

Cattle density is highest in Southwest England, Northwest England, Southwest Scotland and Southwest Wales and lowest in Eastern England (RADAR, 2009). The highest sheep densities are in Wales, Cumbria, Northumberland and Southeast Scotland and lowest in Southeast England, Central southern England and the Highlands (RADAR, 2009). The Muntjac and Chinese water deer populations are therefore away from the highest densities of ruminant livestock. The Sika and Chinese water deer populations are the smallest wild deer populations. This indicates that based on geographic location and population size alone Muntjac, Sika and Chinese water deer are the least likely to come into contact with ruminant livestock and therefore be at risk of hazards transmitted via vectors or aerosol transmission.

Habitat

Shared habitat will increase the risk of transmission via fomites, vector and aerosol spread.

Chinese water deer populations are densest in wet habitats but they can also persist at lower densities in drier habitats including agricultural land although they usually avoid areas being grazed by livestock (Cooke & Farrell, 1981, 1998).

Muntjac deer prefer mixed or deciduous woodland but may occur in other woodlands and scrubland (Chapman & Harris, 1996). Individuals will travel routinely across fields within a home range (Blakeley *et al*., 1997) but they are not a grazing species and do not spend time in open pasture.

Roe deer inhabit open woodland with lower densities in coniferous woodland and higher in agricultural-deciduous woodland mosaics (Hewison & Staines, 2008).

Red deer populations tend to occupy habitats with little livestock such as deciduous and coniferous woodland near open moor and heathland. Some populations however, in particular those in southern and eastern England can be found in improved pastures and crops next to woodland (Staines *et al*., 2008; The Deer Initiative, 2010).

Sika and Fallow deer tend also to inhabit areas where woodland and open land such as pasture, meet. Sika deer may travel several miles each day between their laying up and grazing locations, Fallow deer tend to have core areas which they rarely move outside of (The Deer Initiative 2010).

The habitat of the Muntjac and Chinese Water deer species suggest that contact between these deer and domestic livestock, is less likely to be less than for other deer species. The heath/moorland based Red deer populations are also at a reduced risk.

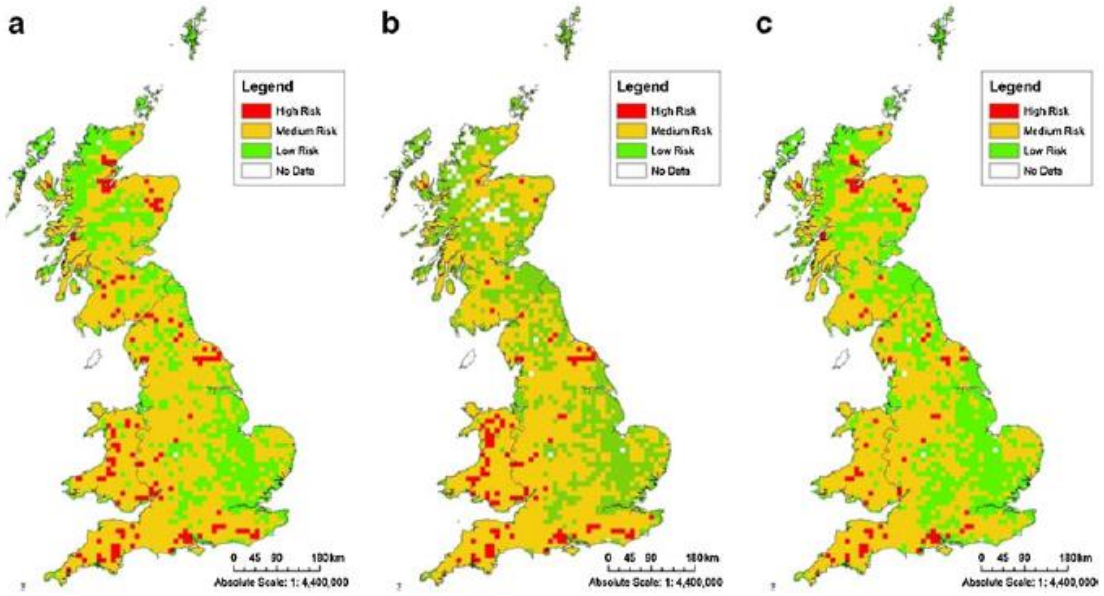

Fig. 2 Maps illustrating the relative risk levels of livestock-wildlife species interactions as an inference for potential disease spread in Great Britain for three species of deer: roe (**a**), fallow (**b**) and red (**c**). This risk analysis drew upon available datasets for deer (10 km^2 grids with presence/absence for 2007), cattle population (June–August average in 2010) and woodland distribution data (2002). The cattle and woodland datasets were each joined to 10 km^2 grids in order to achieve coherence between datasets. The densities of the cattle population and woodland per 10 km^2 were then able to be calculated. All three files were converted to raster (simplified) images and overlaid using GIS. The risk rating was determined through a simple accumulative scale so high risk equated to high deer density, high cattle density and the presence of suitable habitat for the deer (*Acknowledgements: Defra, Fera, Forestry Commission, Cattle Tracing System*

Behavioural Ecology

The behavioural ecology of the deer species has influence over the exposure risk. Deer appear to avoid pasture that contain cattle and when they do share pasture deer tend to only spend short periods of time there (average of 6min 31s for Muntjac, 1min 0s for Fallow deer and 1min 3s for Roe deer; CSL, 2006). Eleven stalker observations of deer and cattle sharing pasture indicated that on two occasions deer were between 11 and 50m away from the cattle and on nine occasions deer were more than 50m away (CSL, 2006). In Italy however, deer have been seen grazing within 3-4m of dairy cattle (Mattiello *et al*. 2003). Red deer preferentially chose to graze areas which have previously been grazed by cattle (Gordon, 1988). In the New Forest, which is a high risk area there is reported niche overlap between deer, cattle and horses (Putman, 1986). Sharing of pasture means that transmission via fomites, insects vectors and aerosol is possible but there is no direct contact between deer and livestock.

Deer social behaviour will influence transmission between wild deer; the number of the in-contact co-specifics influences the ability of a disease reservoir to become established. The size of home territories influences potential for disease transmission

to livestock and other deer herds as it indicates the likely extent of movement of individual infected animals and therefore the geographical range over which that animal is likely to transmit disease. This is also true of juvenile dispersal which again could determine the extent of any infected area.

Chinese water deer inhabit discrete territories in pairs or small family groups; for those which do not have a territory or dispersing young their range is approximately 2 ha for males and 15 ha for females (Crane, 2000; Cooke & Farrell, 1998, 2008). Discrete groups may feed nearby but appear not to interact. Population density is very low in farmland (<2 km^{-2}) and higher in fenland (Cooke & Farrell 2008).

Muntjac deer are territorial and generally solitary yet may coexist with Fallow or Roe deer (Chapman, 2008). Densities vary with habitat estimates from 15-76 km^{-2} (Blakeley *et al*. 1997,White *et al*., 2004, Hemani, 2003) - in predominantly coniferous forest - and up to 100km^{-2} in deciduous woodland (Cooke, 2006). Muntjac territories are vary with population density although most movements within a large forest are less than 4km (Chapman & Harris, 1996). Young deer dispersal varies with habitat and density but can be 13-21 km (Chapman & Harris, 1996; Chapman, 2008).

Roe deer tend to exist as single animals or in small family groups. Males are territorial in winter and territories are approximately 5ha; they will disperse just a few kilometres to create a new territory. Density can be up to 34-76 km^{-2} (Hewison & Staines, 2008) and tends to be lower in pure coniferous and higher in rich agricultural-woodland mosaics.

The social structure of Chinese Water, Muntjac and Roe deer does not favour intra-species disease transmission as the species are territorial and do not form large herds.

Fallow, Red and Sika deer form intra-specific herds, the size of which varies, depending upon habitat type and quality, time of year and level of disturbance (The Deer Initiative, 2010). In the New Forest home ranges for Fallow deer are 50-110 ha, and grow by 50% in the winter. (Langbein *et al*., 2008). Red stags can range up to 40 km during a year and like Sika deer herds can move several kilometres in one day (The Deer Initiative, 2010). In Southwest England Red deer hind ranges are 275-

711ha, and stags are 1000-1200 ha. On Exmoor densities are approximately 3.5-6km^{-2} and on Quantocks approximately 9km^{-2}. Sika deer ranges in Ireland have been recorded at 18--70 ha dependent upon age and sex and young stags may disperse up to 50km (Putman 2008).

The gregarious nature of these species favours intraspecies transmission and the home range size and movement allows for potential spread of the disease.

Risk Mitigation Measures

If wild deer did become infected with a notifiable disease then disease control would need to be considered. The effectiveness of the control measures would heavily depend on the practicalities of locating and culling infected deer. This significantly affects the risk assessment. Hunting and shooting some species of deer is common in GB however other culling other species is more problematic.

Chinese water deer can be conspicuous on farmland, particularly in winter and present an easy target in the flat open landscapes of East Anglia (Cooke & Farrell, 1998). Within large wetland areas where there is dense cover, eradication would be much more difficult and probably impossible (Cooke & Farrell, 1981; 1987; Cooke, 2009b). Shooting Muntjac deer would require a concerted effort to effectively control a population due to their small size and habitat preferences.

Roe deer tend to be the easiest deer to cull due to their established home ranges and predictable behaviour (The Deer Initiative, 2010). Red and Fallow deer may change their behaviour if disturbed and can move over large areas making culling difficult (The Deer Initiative, 2010). Sika hinds will only change their behaviour under continual pressure whereas stags will change behaviour more swiftly and move more following disturbance (The Deer Initiative, 2010). Due to often being found in open areas makes Fallow, Red and Sika deer easy to spot but difficult to approach (The Deer Initiative, 2010).

Locating and then effectively managing a wild deer population would be technically challenging, resource intensive and during a disease outbreak may cause further

dissemination of susceptible animals. Any interventions may not be effective as the success rates of culling are unlikely to be 100%.

Risk Estimation

The overall risk estimation is based on the likelihood of wild deer becoming infected with the specified disease and the consequences for effective disease control resulting from the wild deer becoming infected as defined by the release assessment (Table 4) and exposure assessment (Table 5), respectively. These are combined according to the method shown in Table 6 to an assessment of overall risk.

Table 6 Risk estimation categories used in this assessment

	Exposure Assessment from Table 5				
Release Assessment from Table 4	Negligible	Very Low	Low	Medium	High
Negligible	Negligible	Negligible	Very Low	Low	Low
Very Low	Negligible	Very Low	Low	Low	Medium
Low	Very Low	Low	Low	Medium	Medium
Medium	Low	Low	Medium	Medium	High
High	Low	Medium	Medium	High	High

The overall risk estimation is shown in Table 7.

Table 7 Summary of Risk Estimation

Disease	Release Assessmnet	Exposure Assessment	Uncertainty	Risk Estimation
Bluetongue virus	Medium	Very low medium in red deer	Low	Low (medium in red deer)
Brucellosis spp.	Very Low	Negligible medium (in red)	Low	Very Low (low in red deer)
Contagious agalactia	Low	Very Low	Medium	Low
Enzootic bovine leukosis	Negligible	Negligible	Low	Negligible
Epizootic haemorrhagic disease	Negligible	Low	Low	Very Low
Foot and mouth disease	Very Low	Low	Low	Low
Vesicular stomatitis	Negligible	Medium	Medium	Low
Warble fly	Very Low	Very Low	Low	Very low (low in roe deer)
Chronic wasting disease	Negligible	High	Low	Low

The main routes of introduction would be via livestock or vectors which could equally infect livestock and wild deer. Spread between deer and livestock is most likely for those deer species which share habitat and geographic location with livestock. The

species most at risk are Red, Fallow and Roe deer and the locations of highest risk are areas with deer presence, high livestock density and woodland presence and therefore highest in New Forest, mid-Wales, north Yorkshire and south-west England. The risk of intra-species transmission is highest for Fallow, Red and Sika deer who live in herds.

The risk of release is mitigated through imports legislation, if notifiable exotic diseases were imported into GB then it is likely that they would be first identified in sentinel livestock species and would therefore the risk of transfer to wild deer would be mitigated through the culling of the livestock. The success of culling deer would vary between deer species although the species most at risk are those for which culling would be most successful.

Discussion

There is substantial literature, both experimental and field based, describing infection of deer with disease however surprisingly little of this focuses specifically on the species found in the UK or on pathogens listed as notifiable diseases. The evidence base is particularly sparse for the species of deer non-native to the UK. In fact no assessment of risk can be made for the role of the Chinese water deer in the UK as no papers regarding infection of any of the diseases under consideration could be found.

There is considerably more evidence regarding the epidemiology of notifiable disease in Red deer which contributed to this species being considered the highest risk of being epidemiological significant during disease outbreaks. It should be noted that for the purpose of this study the North America Elk has been assumed to be the same species (but a different subspecies) as the European Red deer and therefore to have equal susceptibility to disease. There was substantial evidence for the role played by Roe deer however this species appears to be less susceptible to the diseases under consideration which reduced the risk associated with this species. There was much greater uncertainty regarding susceptibility and the epidemiology of the diseases in Sika and Fallow deer.

Wild deer population dynamics have a significant effect on the likelihood of the establishment of a disease epidemic or a disease reservoir being established. The increasing deer population means an increasing number of hosts available for the transmission of disease and also a higher contact rate between hosts. Although population size is important, high population density and the associated increased opportunity of transmission from infected or carrier animals to uninfected or naïve animals is more influential.

For some of the notifiable diseases of ruminants, despite extensive searches no reports of the diseases in deer species could be found therefore these diseases could be considered to be of very low risk. If deer were naturally susceptible and infection had occurred it is likely that these events would have been reported through international disease reporting systems however this assessment was considered to have high uncertainty. This situation is true of Contagious Bovine Pleuropneumonia, Lumpy Skin and Rift Valley fever.

It should be remembered that in all of these surveillance programmes differences in prevalence and distribution of infection between deer species and livestock could be caused by the numbers of samples tested, unequal distribution of the *Culicoides* vector species, differences in susceptibility to the vector or pathogen of differences in distribution of the vector and pathogens across the study sites.

The overall likelihood of exotic notifiable disease occurring in wild deer is low**.** This is supported by the lack of evidence of clinical infection and onward transmission of the diseases in deer even in areas of concurrent infection in livestock. There are however some exceptions especially in Red deer. Bluetongue risk is considered as medium due to the BTV virus has been found in wild Red deer suggesting a viraemia which can persist rather than be transient and that the disease is vector borne so that deer could be acting as reservoir for the *Culicoides* midges that transmit the deer. Brucellosis risk in this species was also considered as medium as there is evidence of epizootic infection in Red deer with transmission to livestock in USA but the overall risk is considered low and epidemic infection in deer has not been reported elsewhere and imports of deer to the Europe are not permitted. Similarly the impact of CWD in Red

deer was considered high but as imports are banned from infected countries the overall risk to the UK is considered low.

Warble fly is considered to be of medium risk in Roe deer as this species is the natural host of *Hypoderma diana* and this species of warble fly is very unusual in that it is not strictly host specific and has been recorded as infecting other host species. Warble fly is still endemic in countries which trade with the UK however as Roe deer are not farmed in the UK live imports of this species are considered unlikely.

The overall risk assessment of low is primarily influenced by the low risk of incursion of exotic diseases generally into the UK. Risk assessments supporting this position can be found at www.defra.gov.uk. The risks of incursion are mitigated by a suite of legally enforced measures such as import restrictions, veterinary certification and inspections. It would seem that the import restrictions preventing the importation of cervids from North America designed to protect the UK from introduction of Chronic Wasting Disease also protect to a certain extent against the incursion of Bluetongue Virus, Epizootic Haemorrhagic Disease, Vesicular Stomatitis and *Brucella abortus* as these diseases have only been reported as widespread and endemic in North America. The identification of high-risk areas for disease transmission between wild deer and livestock may help to target disease control at specific high-risk areas.

Conclusion

Qualitative risk assessment provides a useful tool for wildlife disease decision makers who often have to work with an incomplete evidence base and where data is not statistically powerful. The systematic approach to this methodology allows presentation of the available evidence in a clear and transparent manner and allows for uncertainty to be considered. The risk assessment can be updated and revised as new evidence becomes available or new and emerging diseases become of concern. This work and a similar study relating to disease risk in feral boar (Hartley 2010) were undertaken during a review of notifiable disease contingency planning and preparedness and in implementation of the England Wildlife Health Strategy.

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Chapter 6. Risk Management. Development of the England Wildlife Health Strategy – A Framework for Decision Makers

6.1 Authorship statement

Mrs Ruth Lysons was my direct line manager and the policy manager for this area of work. She reviewed the paper and authorised publication. The development of the paper and its content was my work.

6.2 Introduction to published paper

The paper in this chapter (Hartley & Lysons, 2011) describes the development of the England Wildlife Health Strategy and is included in this thesis because it focuses on risk communication and risk management. These two stages of risk assessment are neglected in the peer review literature despite the fundamental role they have in utilising risk analysis in decision making.

In the framework of risk assessment, as described in Chapter 1, risk analysis leads to the activities of risk management and risk communication (Bruckner et al., 2010; Covello & Merkhoher, 1993; Jakob-Hoff et al., 2014). Risk analysis is conducted by the application of objective science and scientific principles, whilst risk management is the decision making process which aims to reduce the likelihood of a negative outcome and/or minimise the consequences of a negative outcome (Artois, Delahay, Guberti, & Cheeseman, 2001; Hueston, 2003). Risk communication is the process of engaging with stakeholders and the public to gain their contributions and opinions on hazard identification, risk pathways and implementation of risk mitigation measures (Hueston, 2003; MacDiarmid & Pharo, 2003). Development of the England Wildlife Health Strategy as described in the paper in this chapter demonstrates risk communication clearly as workshops, symposiums and public consultations were used as different stages of the development process.

Animal health actions adopted by governments are an interplay of science and politics. The policy making process is governed by organisational culture and structures and

constrained by legal authority, politics and resources (Hueston, 2003). Risk management decisions are inevitably, at least partly, social, political and economic decisions and cannot be made based on biological and epidemiological factors alone (Hueston, 2003). Zero risk is seldom, if ever, attainable and some degree of risk is unavoidable therefore value judgements on the acceptability of risk and reasonableness of the costs of control are required (Eduljee, 2000). This is challenging as different stakeholders will define 'acceptable risk' differently and benefits of a particular activity for one stakeholder group may have adverse consequences for another (Hanisch-Kirkbride, Riley, & Gore, 2013; MacDiarmid & Pharo, 2003). Hence the importance of the risk management and communication processes evidenced in the paper in this chapter.

Risk analysis has now been recognised as the tool for applying scientific knowledge to animal health threats as shown in Chapter 2 and elsewhere in this thesis, (Hueston, 2003; Wieland, Dhollander, Salman, & Koenen, 2011) . Risk analysis does not give a single correct answer to a threat but is a step by step exercise using facts and data plus opinions and judgements from a broad variety of perspectives (Wooldridge, 2000). Documentation of the risk analysis and transparency of the risk analysis process are rapidly becoming the norm, as policy decisions regarding animal health must be justified (Eduljee, 2000; Hueston, 2003). Risk communication as illustrated by the paper in this chapter, promotes an open and transparent policy making process and is essential in helping decision makers to deal with what constitutes an 'acceptable risk' (MacDiarmid & Pharo 2003).

Wildlife disease control is not only complex but generates significant public attention and controversy (Artois et al., 2001). At both a national and European level, decisions on wildlife disease control have been based on expert opinion rather than a strategic framework based on scientific evidence (Artois et al., 2001). Public and stakeholder engagement and consultation however, has been limited (Hueston, 2003). Decisions concerning wildlife disease control are often made by politicians, not veterinarians or wildlife scientists (Hueston, 2003; Tompkins & Wilson, 1998). These criticisms regarding the under pinning of policy with robust, transparent science and the importance of the integration of stakeholders, experts and decision makers have been

exemplified by the management of tuberculosis in cattle and badgers in the United Kingdom (Artois et al., 2001; Grant, 2009; Krebs)

In order to respond adequately to disease threats when needed, it is paramount that government authorities and stakeholders agree on policies, procedures and strategies preceding a disease outbreak (Artois et al., 2001; Bar-Yaacov, 2008). In recognition of this and to respond to criticism and concerns regarding the management of tuberculosis the UK Government decided to develop a Wildlife Disease Strategy. A disease strategy is the overall policy agreement and defines the acceptable level of risk for a multitude of different disease scenarios and prepares for the unexpected or unknown. This plan must be agreed at a top level of government and with relevant agencies, stakeholders and industry (Bar-Yaacov, 2008). Beyond this, the strategy considers how evidence for decision making is collected, collated and analysed, identifies knowledge gaps and the processes regarding engaging both expert and stakeholders participation into decision making.

Risk assessment is key to the England Wildlife Health Strategy. The paper in this Chapter explain how risk assessment processes will be commissioned, completed and communicated. The paper then develops this further by using the fundamental processes of hazard identification and risk analysis to determine policy priorities and acceptable risks. This strategy epitomises the concepts of transparent risk management and risk communication approaches by being published. The UK Government took the unprecedented step of submitting the policy strategy to peer review (Hartley & Lysons, 2011).

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6.4 Published Paper

Development of the England Wildlife Health Strategy – A Framework for Decision Makers

M. Hartley & R. Lysons

Abstract

Diseases in wildlife have been recognised as having potential to impact on human health, livestock health and species conservation. In order to assess and respond to these potential risks in an effective and proportionate way the UK government initiated development of the Wildlife Health Strategy to provide a framework for decision making. The England Wildlife Health Strategy (EWHS) has been developed through extensive consultation. Discussions and negotiations with Government departments, agencies, non-governmental public bodies and wildlife organisations were held to obtain advice and input on specific and specialised aspects of wildlife health. A series of workshops to investigate the application of innovative science to wildlife health policy further contributed. A formal public consultation was held which proposed a range of actions to implement the strategy. A summary of responses to this consultation was published in October 2007. The England Wildlife Health Strategy (EWHS) was published in June 2009 and provides a framework for a generic four stage approach to wildlife health which can be adopted by decision makers both within and outside government. The strategy document identifies key areas for further work during implementation which will occur over a three-year period.

Introduction

Wildlife is increasingly recognised as having a significant role in the epidemiology of exotic, endemic, new and emerging diseases that pose risks to humans, livestock,

biodiversity conservation and economic productivity (Daszak et al, 2001; Sainsbury et al, 2001).

Wildlife populations have long been considered a link in the chain of pathogen emergence by forming the reservoirs from which zoonotic pathogens may emerge. 60.3% of human emerging infectious diseases are zoonotic, 71.8% of these were caused by pathogens with a wildlife origin (Jones et al, 2008). Examples include nipah virus (Jones et al, 2008) and west nile Virus (Meagher & Waage, 2005).

Of the 38 livestock diseases that are notifiable and therefore subject to compulsory control or eradication, under European legislation, 23 have wildlife hosts . Wild animals can be reservoirs of OIE (World Animal Health Organisation) listed diseases (Morner et al, 2002) and therefore wildlife disease monitoring programs are increasingly part of proving national disease freedom status, which is important for maintaining and increasing international trade. These include classical swine fever and rabies (Artois et al, 2001). The inter-relationships between livestock and wildlife create the potential for transmission of pathogens in either direction, from wild animals to domestic animals or vice-versa.. A number of wildlife emerging infectious diseases have emerged due to “spill-over‟ from domestic animals into wildlife populations. These diseases can then “spill-back‟ into domestic animals which may then create a conflict between conservation and commercial interests (BENGIS et al, 2002).

Infectious and non-infectious diseases can have a significant impact on the dynamics and conservation status of populations (Scott, 1988; Deem et al, 2001; Chomel et al, 2007). Defining the diseases, which have an impact on threatened wildlife, is now considered integral to rehabilitation programs for remnant wildlife populations and in captive breeding programs designed to restore healthy animals to the wild (Woodford & Rossiter, 1993; Leighton, 2002; Morner et al, 2002). Examples include amphibian chytridmycosis, crayfish plague and pox virus in red squirrels.

In addition wildlife health and welfare issues have a high public profile. Recent disease outbreaks including trichomonas in garden birds and avian influenza have raised this further. The public expect that the welfare of wildlife, including the impacts of disease should be monitored (Kirkwood & Sainsbury, 1996).

Apart from the direct economic, public health and trade implications of the presence of diseases in wildlife, overt disease outbreaks and mass mortality in wildlife may be important indicators of ecological disturbance, introduction of new animal species,

emergence of new diseases, climatic or habitat change or pollution (Sainsbury et al, 2001; Morner et al, 2002). In order to assess and respond to these potential risks in an effective and appropriate way the UK government initiated development of the Wildlife Health Strategy.

Background

In 2001 the UK Ministry of Agriculture, Fisheries and Food was merged with the Department of the Environment to create the Department for Environment, Food and Rural Affairs (Defra). This created a single government department that had responsibility for policy with regard to animal health and agricultural policy as well as biodiversity and environmental policy allowing a holistic approach for wildlife health to be developed.

The Animal Health and Welfare Strategy (AHWS) (Defra 2004) provides the framework of the British government's approach to veterinary intervention. Alongside this a UK Veterinary Surveillance Strategy was published in 2003 (Defra 2003) with the objective of enhancing and coordinating national veterinary surveillance so that important animal health events are detected and assessed more rapidly and reliably. These strategies, although heavily focused on domestic livestock, clearly identified the potential role of wildlife in disease surveillance and mitigation but recognised that there were significant differences in the approach and partnerships required to implement the two strategies with regard to wildlife. Therefore the England Wildlife Health Strategy has been developed to operate in parallel to these two overarching strategies and take forward their aims and objectives but adapted into an appropriate wildlife context.

Methodology

An initial scoping study identified that, in order to develop a wildlife heath strategy, additional specialist resource would be required. Therefore in late 2005 a wildlife veterinary adviser with postgraduate training in wildlife health and a background both

in free-ranging disease investigation and conservation was appointed to lead development of this strategy.

The initial stage of strategy development was to identify and consult with the core government policy making directorates and delivery agencies with a potential interest in wildlife disease. The complexity of the task ahead became apparent as it was realised that wildlife health is impacted by and contributes to factors monitored and managed across national government both in central departments and an array of delivery agencies.

From this group a formal project board was established to provide governance of the strategy development and to ensure engagement from across government and also with stakeholders. The members represented the Defra veterinary directorate, Defra biodiversity directorate, Defra's Veterinary Laboratories Agency who conduct laboratory-based animal disease surveillance in England and Wales, the Food and Environmental Research Agency, the Health Protection Agency of the Department of Health, and two non-government wildlife disease experts from academia and charity sectors. The project board met on a bi-monthly basis to review progress and guide development of the strategy using the feedback from a variety of stakeholder workshops and consultations, the details of which are described. The strategy continued to be developed through extensive formal and informal consultation.

In June 2006 a large workshop attended by 100 organisations was held to engage with stakeholders both within and outside of government and to further develop and challenge early thinking (Defra, 2006). Foresight (2010) is a government funded programme, led by international scientists, investigating the application of innovative science in policy making. In May 2007 a technical workshop was held in conjunction with the Foresight initiative as part of it's project on detection and identification of infectious diseases in plants, humans and animals (Defra, 2007a).

In July 2007 a formal 12-week public consultation was published (Defra, 2007b). The twenty questions focused on how stakeholders could work in partnership with government and what issues they considered as a priority. 49 responses were received from academia, non-governmental organisations, the public sector and private individuals. A summary of responses to this document was published in October 2007 (Defra, 2008).

Further challenge to the developing strategy was provided by the Parliamentary Office of Science and Technology (POST) which is the UK Parliament's independent source

of balanced analysis of public policy issues and aims to inform parliamentary debate. POST published a briefing note examining the impacts of wildlife diseases, the current status of surveillance in the UK and options to strengthen policies (POST, 2008).

A final stakeholder workshop was held in November 2008 to focus on the impacts of wildlife disease on biodiversity and threatened species. It was recognised that this issue needed to be considered with a cadre of different stakeholders utilising some novel approaches.

In addition to these specifically designed workshops, officials attended a wide range of national and international veterinary and conservation conferences presenting the developing strategy to experts seeking input and challenge.

The early workshops and public consultation identified some principal issues;

- Variable recognition of the risk factors that influence the occurrence of wildlife disease and its potential impacts.
- Roles and responsibilities in regard to wildlife disease are complex, ill defined and in many cases shared.
- That there was little co-ordination, co-operation or consistency in the way wildlife disease issues were assessed or managed.
- Creation of a single wildlife health policy owner or single delivery agency was not feasible. Instead wildlife health issues need to be considered and included in policy areas across government.
- A number of established and successful projects focused on wildlife disease issues and that these should not be negatively impacted by development of a strategy but that there could be opportunities for sharing of resources and effort.
- There was already a wide range of surveillance, pathological and ecological information being collected on wildlife diseases however it is not readily available or easily shared. Data quality, compatibility and ownership were key issues.
- Although specialist wildlife veterinary experts were employed by government they were not readily accessible to all that needed advice.

- Key areas of concern were impact of non-native species, potential disease risks from rehabilitation of wildlife, poisoning of wildlife, improving wildlife disease surveillance, over abundance of some species, zoonotic diseases and disease impacts on conservation.

Due to these complex challenges it became apparent that before the strategy could be developed further, careful consideration was required to define the final product that was required and that would be effective. This required that stakeholders all shared an agreed understanding of the aim, scope and vision, the definitions of these terms is shown below.

Aim

The high level purpose of the strategy was agreed in the first stakeholder workshop in early 2006 which reflects the realisation that the strategy would not be able to respond to individual diseases or scenarios as there were so varied and specific but rather a consistent and scientifically justifiable approach to policy making was required.

*"*The Wildlife Health Strategy provides a framework within which Government and others will be able to develop and make policy choices and decisions in relation to wildlife disease management based on sound scientific evidence through better co-ordinated collaboration and responsibility sharing*."*

Scope

The scope of the strategy relied on a clear understanding of the issues and impacts that government has a social responsibility to intervene in and which are an appropriate use of UK tax payers money.

The Great Britain Animal Health and Welfare Strategy (Defra, 2004) clearly defines four key reasons for government to intervene in animal health issues. These are:

- Protection of human health
- Protection of domestic animal health and welfare
- Protection of international trade
- Protection of society and the wider environment.

Whilst these reasons for intervention are relevant to domestic animal diseases these did not reflect all of the responsibilities that government has in regard to wildlife. Both domestic and European legislation requires government to protect the environment and biodiversity. As diseases can impact on wildlife species and therefore ecosystems, conservation is increasingly a reason to intervene in wildlife disease issues; however a balance had to be achieved as it is recognised that disease is a natural phenomenon and that native wildlife species have evolved to live with endemic diseases and whilst individuals and local populations may be effected this is part of natural ecology and is not a reason for government to intervene. It was therefore decided to add an additional reason for governmental intervention.

- Protection of biodiversity and threatened species

An important caveat was added which was that government would intervene only when the impact was significant enough to cause a decline in population viability of a species officially recognised as of conservation concern or a situation where the impact was so severe that a species could become threatened.

It also became apparent that there are many definitions of the term 'wildlife' with some people considering plants, captive or zoo animals or even exotic pets as falling into this category. Due to the array of existing legislation with regard to animals kept or owned by humans the following definition was agreed upon.

*"*This strategy includes native or non-native species of land or water animals currently free-living in England, whether resident or visiting migrants. It includes species with the potential to occur in the wild in the near future. Plants are excluded*."*

Further consideration of the term 'health' was also required. The definition used in the strategy is:

"Wildlife health includes negative impacts on animals caused by infectious diseases non-infectious conditions, poisons, toxins and contaminants."

In the United Kingdom animal health policy has been devolved to the independent administrations of England, Scotland, Wales and Northern Ireland therefore each country may, and indeed do, implement different policies and delivery arrangements. Due to the already complex network of delivery agents, imminent elections to the Welsh Assembly and Scottish Government and limited resources it was decided to confine the wildlife health strategy to England but to maintain communication and co-operation with the other administrations.

Vision

The vision was defined more slowly and was adapted as the stakeholder engagement and strategy development progressed and the appropriate outcomes became clearer. "The over-riding vision for this strategy is for the disease status of wildlife to be considered and balanced with society's interests and responsibilities, including human health, economic activity, biodiversity, the health of kept animals, and the need for a responsible approach to human/wildlife interactions. This will be achieved by:

- taking a holistic and co-ordinated approach to wildlife health across government and interested parties.
- taking a proportionate, risk-based approach to wildlife disease surveillance and prevention; and
- making appropriate and proportionate interventions where necessary"

The Four Stage Approach to Wildlife Health

The expert opinion, public consultation and workshop outputs were analysed and considered by the project board and it was determined that The England Wildlife Health Strategy needed to provide a structured and transparent approach for assessing and responding to wildlife health issues in order to allow effective decision making. It needed to identify appropriate tools and techniques that could be utilised in this process considering how existing processes and systems could be adapted for use in wildlife thus allowing consistency and prioritisation with livestock health management. It also needed to identify areas of further investigation and development for the strategy's implementation stages.

A simple four-stage process was constructed (see figure 1).

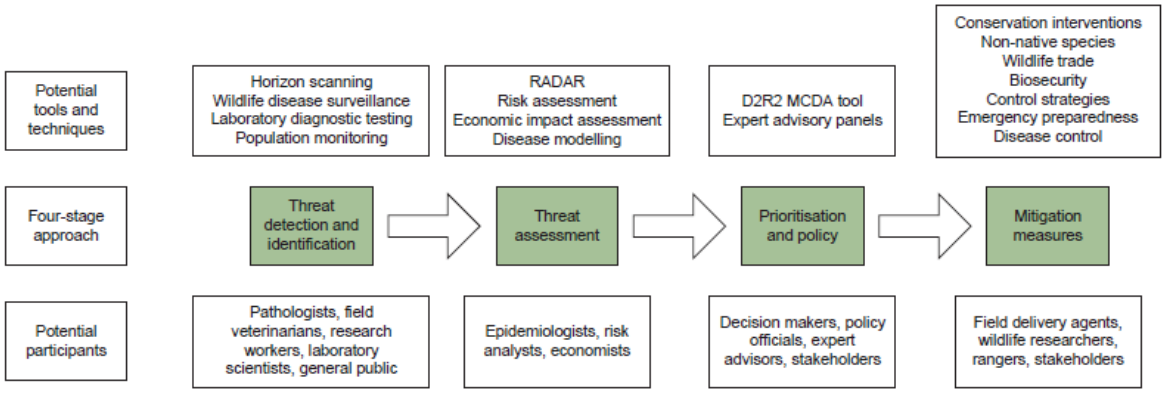

FIG 1: Four-stage approach of the England Wildlife Health Strategy showing potential tools and participants. D2R2 MCDA Disease briefing, Decision support, Ranking and Risk Assessment Multi-Criterion Decision Analysis Tool

The stages were devised recognising separation of responsibilities and expertise. So for example surveillance and diagnosis of disease would be undertaken by field veterinarians and working with laboratory scientists whilst risk assessment and data analysis would be undertaken by epidemiologists and decision making by policy officials. Each stage could then be developed and managed by relevant sectors but guided by the cohesive EWHS. At each stage the document describes potential sources of evidence to be considered or techniques that could be utilised that were identified during strategy development. Finally key actions were determined which would be required to implement the England Wildlife Health Strategy.

1. Threat Detection and Identification

The first stage is the recognition of potential threats. Four key methodologies were identified these were horizon scanning, veterinary surveillance, laboratory diagnosis and population monitoring.

Horizon scanning has been defined by Defra (2010a) as 'The systematic examination of potential threats, opportunities and likely future developments which are at the margins of current thinking and planning. Horizon scanning may explore novel and unexpected issues, as well as persistent problems or trends.' Horizon scanning for diseases allows for early recognition of potential threats, risk assessment and planning of mitigation actions. Potential sources of information include both official disease reports such as to the OIE or unofficial disease reporting forums such as ProMED (International Society for Infectious Diseases, 2010). Little work has been undertaken on horizon scanning methodologies specifically for wildlife diseases. A particular recommendation from the work undertaken by Foresight was that governments should investigate the potential benefits and uses of horizon scanning as a component of their disease surveillance programmes (Foresight, 2010).

Veterinary surveillance is defined as the on-going collection collation of information about disease, infection or intoxication in a defined animal population for the purpose of detecting changes in the effects of disease on the defined population (Defra, 2003). Defra has funded wildlife surveillance through the Veterinary Laboratories Agency Diseases of Wildlife Scheme since 1998 (Veterinary Laboratories Agency, 2010).

Recommendations for improving veterinary surveillance in England are described in the Veterinary Surveillance Strategy (Defra, 2003), and progress with its implementation was reported in 2007 (Lysons et al, 2007). One of the major drivers for Defra to develop the EHWS was to implement the Veterinary Surveillance Strategy in regard to wildlife species and indeed some progress had been made towards this; however it was recognised that a full review of the government's roles, responsibilities and objectives in relation to wildlife health was needed to pursue this. Stakeholders agreed that the work streams of the VSS: namely strengthen collaborations; development of a prioritisation process; derive better value from surveillance information and activities; sharing information more widely; enhance the quality assurance of outputs; were directly relevant and should be adopted to guide further development of wildlife disease surveillance in England.

Laboratory testing of pathological samples from wildlife species is utilised where tests are available to identify the presence or absence of an infectious or toxic agent. In wildlife species this is not always straightforward as the test is often not validated for wildlife species and have poor sensitivity and specificity, making interpretation difficult. (Artois et al, 2001; Stallknecht, 2007). This impacts on the rapid identification and confirmation of diseases and therefore has consequences to human health, livestock health, conservation, trade and food security.

Population monitoring, including assessment of both density and distribution of wildlife over time, allows an alternative approach to disease surveillance be adopted. Whilst the three other techniques assume that a negative impact on wildlife health has been identified and then aim to characterise it, population monitoring identifies that there is a negative impact on populations, which may or may not be a health impact and indicates that further investigation is necessary to confirm that a disease or toxin is causing the effect. Population monitoring is particularly important for identifying threats to small populations of wildlife species. This technique is not used frequently in domestic animal disease and this data is often collected by organisations that do not routinely work with disease issues and therefore do not recognise the value of this data for this purpose.

A clear route of escalation of potential wildlife disease risks from those whom have identified them to those whom can respond and initiate actions is essential. An understanding of the information required by decision makers in order to respond to risks with appropriate and proportionate mitigations is key to moving onto stage 2 in the process. Even more fundamental is ensuring that escalation is directed at the appropriate decision makers who understand and 'own' the potential risks identified. These were all issues identified in

2. Threat Assessment

The evidence collected in stage one then must be collated and analysed so that the impact of the threat can be assessed in a scientifically sound and transparent manner. This often involves combining information from a number of sources using specific and specialised techniques. At this stage the potential risk factors and drivers of the identified wildlife health threat need to be considered. These may include habitat alteration and land use, animal movements, climate change, population pressures and anthropomorphic effects such as international trade and introduction of non-native species. (Dasak et al, 2001; Morner et al, 2002; Williams et al 2002; Kuiken et al, 2003)

As part of the Veterinary Surveillance Strategy (VSS) a surveillance information management information technology system called RADAR (Rapid Analysis and Detection of Animal-related Risks) has been developed (Defra, 2010b). The system links, collates and analyses data from many different sources. The reports produced highlight the risks and distribution of animal diseases and their risk factors. This tool can be used for analysing wildlife data provided by a range of stakeholders. RADAR includes geographical information systems which facilitates risk mapping. Epidemiological investigations gain strength from being able to incorporate information about proximity of relationships between animals at risk and the spatial distribution of risk factors (Pfeiffer & Hugh-Jones, 2002). Challenges include data use and confidentiality, data quality and technical integration of data collected in different systems.

Risk assessments are routinely used for veterinary policy making in England. Risk Assessments consider the likelihood of specific scenarios occurring and the consequences resulting from the event. Defra veterinary risks assessments are

presented in a consistent format to allow comparison between issues and include veterinary technical information, legislative requirements and public values (Defra 2010c).

An additional tool is disease modelling which uses defined assumptions to allow calculation of scenario probability and impact or the feasibility and effectiveness of mitigation measures. This can be combined with cost-benefit analysis which allows assessment of the cost effectiveness of different policy decisions or mitigation actions.

3. Prioritisation and Policy Development

The complete, processed information must then be considered and prioritised against numerous other risks that the public, livestock, the economy and biodiversity are exposed to. As part of implementation of the VSS, a multi-criteria decision analysis support tool for prioritisation has been developed. This is based around disease profiles which contain key information. These are written, peer-reviewed and validated by experts. The profile information is then scored and a ranking produced against the government's reasons for intervention from the Animal Health and Welfare Strategy. The Disease Briefing, Decision Support, Ranking and Risk Assessment Tool (D2R2) will be used where possible to assist in prioritising interventions by government and to ensure a transparent and consistent process for policy making (Defra 2010c) .

A number of technical expert advisory groups are utilised in order to formulate recommendations for decision makers in regard to livestock and human health. These groups include representation from government departments and agencies with responsibility for identifying, assessing and mitigating the high priority risks. In many groups external experts participate. The groups ensure that the scientific evidence is of sufficient quality and completeness for decision making.

It is essential to base policies on wildlife health on sound science, but also to consider ethical and social factors which impact on stakeholders (Artois et al, 2001). Final decisions on interventions would be taken by senior decision makers or on occasions government ministers using the evidence and expert recommendations provided.

4. Mitigation Measures

Once a decision has been made to intervene it must be ensured that action is appropriate and proportionate and that responsibilities are shared fairly between

government and others. The EWHS outlines the high-level approaches that can be considered, the potential transmission pathways that should be considered and outlines the tools and legislation which could potentially be used to minimise disease risks.

Preventing disease entering wild animal populations is the most efficient and cost-effective way of managing wildlife disease (Wobeser, 2002). It is therefore necessary to consider sources of introduction of disease into wildlife populations. Translocations of wildlife for conservation, agriculture and hunting occurs on a global scale with inherent risk of disease introductions (Morner et al, 2002: Williams et al, 2002) . Captive breeding and re-introduction programmes could also pose a risk if sufficient care is not made to disease screening before release (Cunningham, 1996). The introduction of non-native species into the wild has been demonstrated to be a high risk activity, examples include the introduction of pox virus into native red squirrels by the carrier grey squirrel (Sainsbury et al, 2000).

Global trade in wildlife provides transmission mechanisms for disease outbreaks. (Karesh et al, 2005). International importations in to the United Kingdom are undertaken according to the trade rules set down by the European Commission and OIE which operate to reduce the risk of disease transmission. These are applied to the majority of mammals and birds.

Once a disease has entered wildlife population, biosecurity measures can be implemented to prevent onward transmission to livestock and disease prevention guidance can be provided to reduce exposure to humans to zoonotic wildlife diseases (Wobeser, 2006).

The active control of disease in free-ranging wildlife is an emerging field and disease control programmes must be planned within a series of practical constraints. The primary decision is to determine the desired outcome, either elimination or management of the disease within defined limits (Wobeser, 2006). Each disease scenario will be very different and therefore it is beyond the scope of the strategy to define which techniques should be used. The options available, at a high level are population management or clinical treatment (Artois et al, 2001). Population management may involve manipulation of population size, structure or contact between host species using culling, fertility control, translocation or restriction (Artois et al, 2001). Veterinary clinical interventions are technically constrained by the

availability of suitable drugs or vaccines and efficient delivery to a high enough proportion of the affected population (Wobeser, 2002) .

The EWHS recognises the challenges faced when attempting to mitigate wildlife disease and recommends development of wildlife specific contingency plans for diseases of concern which could involve wildlife. Development of these plans allows for the identification of knowledge gaps and therefore where further collection of evidence or disease surveillance could usefully be undertaken (Wobeser, 2002). It also will allow confirmation of roles and responsibilities during a disease outbreak and for delivery arrangements to be planned.

Communications

Communications regarding the development and implementation of the strtagey were considered in a separate work stream. Diseases of wildlife are of concern to the general public and generate considerable coverage by the media (Kirkwood, 1993, Artois et al, 2001). It is essential that the public and stakeholders have access to well-balanced, accurate, scientific information, including the work that Government undertakes or funds on their behalf. Transparent decision making, supported by accessible science, should ensure that the links between wildlife diseases and national biological security, trade, conservation and public health are clear.

A wide range of stakeholders undertake work independently or in partnership with Government, well managed information exchange is a key tool for horizon scanning, disease surveillance and collection of scientific research.

Successful implementation of the EWHS will rely on effective communication of the strategy and the actions taken during the implementation phase. A number of novel web based tools could be used in addition to traditional web pages.

Implementation

For each component of the four-stage approach and the communications work stream, a high level implementation plan was developed (Defra, 2009). These key actions will be undertaken in the next three years with progress being reviewed in 2012.

Publication

The draft strategy was circulated widely for comment and input with the final version being endorsed by three government departments and 19 agencies or public bodies.

The England Wildlife Health Strategy was published in June 2009 following final approval by both the Chief Veterinary Officer and Defra Ministers (Defra, 2009).
The strategy has generally been welcomed by stakeholders with several positive reviews in the specialist press, but some disappointment that it does not specifically address individual diseases. It was considered that each individual disease issue will require managing in a specific manner due to different reasons for intervention, populations of concern, techniques available and resources allocated. Although the principles set out in the EWHS are applicable, a single generic solution to the impacts of wildlife disease is not feasible. Concern was also expressed in relation to funding. Whilst all sources of funding are under pressure from the current stringent fiscal circumstances, implementation of the EWHS should realise benefits through harnessing synergies between potential delivery agents, and introduction of a more efficient approach to decision making in this area by appropriate utilisation of the four-stage approach described above.

Conclusion

This paper describes the development of the England Wildlife Health Strategy from initial concept through to publication. The framework described here provides a generic approach to wildlife disease issues and outlines potential tools or techniques required to apply this. The strategy recommends further work and areas of investigation which could further develop and improve identification, assessment and mitigation of wildlife diseases in England. This work will be undertaken during the implementation process. Implementation of the England Wildlife Health Strategy will be described in a further paper in due course.

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Chapter 7. Risk Analysis as a Tool for Disease Investigation in Zoo Health Management

7.1 Authorship Statement

Mr Derek Grove and Mr Matthew Lewis are animal curators at Dudley Zoo and managed the animals under investigation. Mr Peter Stewart MRCVS is the Dudley Zoo Veterinarian and undertook the clinical veterinary work. Developing the risk based decision framework for the disease investigation and writing the paper was entirely my work.

7.2 Introduction to published paper

In this Chapter the paper by Hartley, Grove, Lewis and Stewart (2014) applies the principles of epidemiological risk based investigations to disease investigations in a zoo environment where there is often much uncertainty concerning routes or transmission, species susceptibility and diagnostic reliability (Chomel & Osburn, 2006). The paper indicates and supports recognition of the important role of risk based approaches for providing evidence to generate preventative guidelines and formulation of contingency plans (Bender et al., 2004).

Risk analysis techniques were originally developed to assess impacts of environmental exposures on human health (Harvey, Mahaffey, Velazquez, & Dourson, 1995) so it is not surprising that the techniques were adopted to investigate both actual and potential exposure to disease. A total of 61% of known human pathogens and 75% of new and emerging pathogens are potentially zoonotic diseases (disease transmitted between humans and animals) (Taylor, Latham, & Mark, 2001) so the interface between animal and public health is critical in this regard (Chomel & Osburn, 2006; Palmer, Brown, & Morgan, 2005).

Risk analysis techniques are fundamental to public health epidemiological investigations (Palmer et al., 2005). Human health professionals have introduced risk analysis techniques to zoo veterinarians and professionals when zoos are implicated in outbreaks of zoonotic disease. To date these outbreaks have mainly focused on

scenarios when members of the public have been exposed to infectious enteric pathogens during animal handling and feeding activities (Bender, Shulman, & Natl Assoc State Publ Hlth, 2004; Stirling et al., 2008). The same approaches are relevant to investigating occupational health risks for zoo staff for a broader range of diseases (Forsyth, Morris, Sinclair, & Pritchard, 2012; Mazet, Hunt, & Ziccardi, 2004; Murphree, 2011; Sandstrom et al., 2000; Stephens et al., 2013).

Although there are a number of papers describing these disease investigations in humans where the source is suspected to be a zoo, they often only state that a risk assessment was completed and forms the basis of the study (Stephens et al., 2013). i.e. the risk assessment is not presented. This does not allow either transparency or a transfer of knowledge in adapting risk analysis techniques to different scenarios or examples of the reality of evidence-based decision making (Palmer et al., 2005). Although focused on a specific scenario, the paper in this chapter, provides a model for use in other structured disease investigations in a zoo environment.

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7.4 Published paper

Risk based testing programme for *Mycobacterium bovis* following a clinical case in a zoological garden.

M Hartley , D Grove , M Lewis , D Beeston, and P Stewart

Abstract

Mycobacterium bovis is a strictly controlled disease. Outbreaks in zoos result in animal movement bans, disease investigation and euthanasia of infected animals. Both specific tuberculosis legislation and European Directive 92/65, often know as the 'Balai' directive require zoos to be free from tuberculosis in order to import and export animals. This paper describes the use of a risk based targeted testing programme for tuberculosis following a confirmed case of disease. This regime ensured a comprehensive but proportionate disease investigation developed through close co-operation with government veterinary officials, therefore limiting the impact of anaesthetic procedures and animal handling required to complete the necessary testing.

Introduction

Tuberculosis is a zoonotic disease caused by bacteria of the *Mycobacterium tuberculosis* complex. Tuberculosis infection, caused by several species of mycobacterium, have been reported in zoological collections.

Mycobacterium tuberculosis was suspected to have been transmitted from infected human visitors, on multiple occasions to a range of primates, antelope and tapirs (Michel et al, 2003). Several reports of outbreaks of the newly identified *Mycobacterium pinnipedi* describe cross species transmission, including to a human, originating from infected sealion reservoirs (Moser et al, 2008; Jurczynski,et al, 2011).

Mycobacterium bovis is the cause of tuberculosis in cattle and has been reported in zoo felids where it is though to have been transmitted from infected meat (Helman et al, 1998, Thorel et al, 1998)). Primates have also been infected on several occasions (Wilson et al, 1984, Thorel et al, 1998) There are surprisingly few accounts of this disease in antelope, deer and camelids in zoos although it is known these species are susceptible as it is seen in wild, ranched and farmed animals (Bengis, 1999).

M.bovis is widespread in the United Kingdom and is subject to official disease control measures. Holders of susceptible animals are required to test stock for the disease and infected animals are culled. In the UK the badger (*Meles meles*) is an important reservoir of the disease (Corner et al, 2011).

Tuberculosis is of very high concern to zoological collections due to the potential public health risks, the potential loss of rare or endangered animals and the impacts of national disease control measures enforced on infected premises, which, include a ban of imports or exports to the site and thus preventing participation in conservation breeding programmes.

In Europe, Directive 92/65 EC, known as the 'Balai Directive' provides a basis for institutes such as zoos to become approved for use of a less stringent animal import procedure following implementation of a comprehensive programme of veterinary intervention including, disease surveillance, preventative medicine, post mortem investigation and isolation procedures. This affords the zoo the benefits of revised animal health certification, reduced pre and post import disease testing and avoids the need for officially supervised quarantine. In order to gain and retain 'Balai approved' status the zoo animals must be free from mycobacterium infection.

This paper describes the implications of a case of *Mycobacterium bovis* infection in an animal held in a zoo approved under Directive EC 92/65 and how risk-based investigations and disease testing were utilised to allow disease control measures to be lifted and re-approval under this legislation to be reinstated.

Background

A pair of llama *(Lama glama)* were tested using a comparative intra-dermal skin test in the auxillary region, for routine disease surveillance purposes. The animals appeared healthy. They had been imported into the zoological collection nine months previously from a local private holder who had not had cases of tuberculosis on their property. When re-examined 72 hours later, no reactions were seen and the animals were accepted as being free from *Mycobacterium bovis* infection.

One week after this test, the male animal was reported as being disorientated, weak and anorexic. On examination it was pyrexic and had an increased respiratory rate. Over the next 10 days the animal's condition developed displaying ophisthotonus, paddling and other neurological signs. The animal was euthanased and the carcass submitted for pathological investigation. This demonstrated both gross and microscopic signs consistent with mycobacteriosis and samples were submitted for bacteriological culture. Infection with *Mycobacterium bovis* was confirmed.

Due to this finding, the zoo's Balai approved status was revoked and the zoo was placed under a Movement Prohibition Notice under the Tuberculosis (England) Order 2007. This resulted in the zoo being unable to move any animals susceptible to bovine tuberculosis until the premises was officially declared tuberculosis free by the official government veterinarians. A disease investigation was initiated to identify the source of infection, any transmission to other animals in the zoo and to facilitate eradication of the disease on the zoo site. This disease investigation was conducted under the direct supervision of government veterinary officials whom reviewed and approved the criteria used to determine the targeted testing programme. The diagnostic test regimes used in this official investigation are set out in UK law under the Tuberculosis (England Order) 2007. Any animals found positive for tuberculosis would be destroyed in order to return the zoo to its disease free status.

Action

The concepts of the OIE Risk Analysis Framework (1994) were applied to this investigation using the risk question ‘ What is the likelihood that M.bovis has been transmitted to other animals in the zoo?’

The standard risk terminology for this framework was used as shown in Table 1

Term	Definition
Likelihood	Probability; the state or fact of being likely
Likely	Probable; such as well might happen or be true; to be reasonably expected
Negligible	So rare that it does not merit to be considered;
Very low	Very rare but cannot be excluded;
Low	Rare but does occur;
Medium	Occurs regularly;
High	Occurs very often.

A risk pathway was produced, see Figure 1.

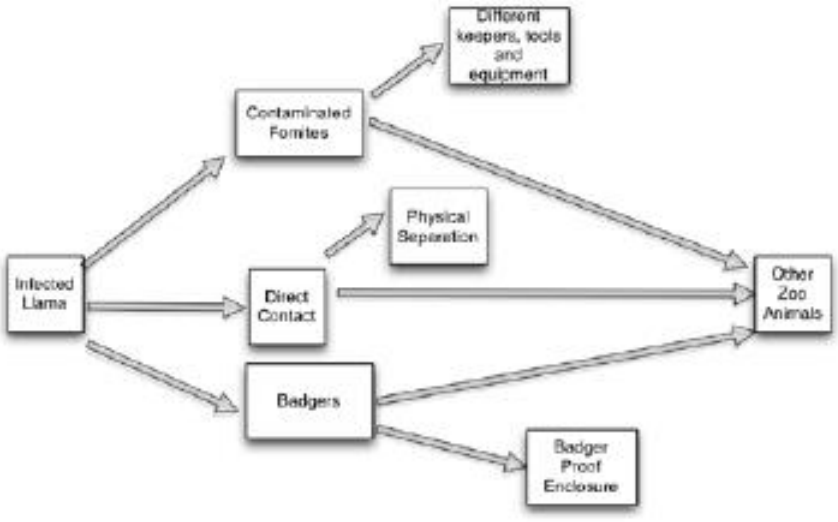

Figure 1. Risk pathway.

Transmission of tuberculosis can be by a number of routes, these include direct contact, short distance aerosol, contaminated fomites or reservoir species. The diagram below was used to identify which animals could have been a source of the

disease and which could possibly been infected by the llama. The highest risk animal was the female llama, this is the only animal the male llama had been in direct contact with since his arrival at the zoo. There were no other animals within proximity of aerosol transmission.

The llamas were cared for by a team of keeping staff who could have inadvertently transmitted the disease on clothing, tools or other equipment and therefore all susceptible species cared for by the same keepers were considered a higher risk of infection. It was unlikely that susceptible species cared for by other keeping teams would be at risk as all equipment was kept separate and only used within a specific house or area.

The final risk factor considered was wildlife reservoirs. The zoo does have a number of setts of the European badger on its site and in theory could be the source of the infection or transmit the disease to other zoo animals. Any dead badgers found on site were examined for evidence of disease and due to the lack of previous cases of *M.bovis* in the badgers in the zoo it is likely that the resident population was free of the disease.

The badger population on the zoo site is isolated from other populations, separated from them by major roads and heavily populated urban development. The nearest cattle and badger populations are significantly beyond the foraging or dispersal range of the species. This significantly reduces the risk of badgers being the source of the infection. However the badgers move around the zoo freely and can enter some enclosures and therefore could have become infected and could be a risk for onward transmission. As the badgers were rarely seen during daylight hours, those species that were housed over night or had enclosures, which prevented access to the badgers were excluded from the investigations.

So in summary the animals that were of highest risk of being infected were the animal in direct contact with the infected llama, those susceptible animals cared for by the same keeping team as the llama and those susceptible animals that may have had contact with badgers. The

Table 2 – Risk Assessment

Source of TB	**Justification**	**Risk Assessment before further testing**	**Risk Assessment after further testing**
Direct contact with infected zoo animals	Only had contact with female llama	High to female llama, Very Low to all other stock.	Negligible – PME examination negative
Indirect contact through contaminated fomites	All other animals cared for using same tools and keepers etc.	Medium	Very Low – all in contact animals tested negative
Infection carried by badgers to other susceptible stock	No evidence of badgers infected with TB on site. Only reindeer and camelids have potential contact with badgers other than llamas.	Low	Very Low – all other stock tested negative

This risk assessment determined which animals needed targeted testing for *M.Bovis* to identify spread of the disease. As the risk of the female llama being infected was high and ante-mortem testing already having been proved unreliable, it was decided to euthanize this animal so that definitive investigations could be undertaken. The animals cared for by the same keepers were Bactrian camels (*Camelus bactrianus*), guanaco *(Lama guanaco)*, alpaca *(Lama pacos)*, domestic sheep, domestic goats and domestic pigs. The camelids could also have had contact with the badgers. The only susceptible species other that could have had contact with the badgers were the group of reindeer *(Rangifer tarandus)* which are located closest to the llama exhibit.

All of the animals were tested using comparative intra-dermal skin tests except for the Bactrian camels which were tested using lateral–flow rapid tests (RT) as described by Dean and others (2009). These are the diagnostic tests, which are required to be used by UK law in these species.

Government public health authorities were notified of the outbreak but due to the routine vaccination of humans in the UK, lack of reported clinical signs in the keepers, that this outbreak was due to *M.bovis* and that an official veterinary investigation was being undertaken the zoonotic disease risk was very low and no action other than biosecurity precautions needed to be taken.

Consequences

The post-mortem examination and bacterial culture from the euthanized female llama did not demonstrate infection with *M.bovis.* The two camels had negative serological tests. All of the animals that were tested using comparative intra-dermal skin testing were negative except a single 16-week old reindeer calf and a domestic goat which both had inconclusive tests. Therefore these animals needed to be retested at 120 days and 60 days post the initial test respectively. These animals were found to be negative on re-testing using the same methodology.

This testing programme demonstrated that the risk of transmission of *M.bovis* from the original animal to others on the site was very low to negligible. The specific testing was supported by the zoos ongoing programme of clinical examinations and routine post-mortem examination of all animals that die. On the very rare occasion a badger carcasses found it is also examined for signs of disease.

As no other animals were found to be infected it was concluded that the source of the disease was the male llama and that it is likely he was latently infected when brought onto the zoo. This is supported by the fact that the female llama was not found to be infected. This animal had been at the zoo for longer than the male and they had only been housed together.

As all the at-risk the animals had tested negative and therefore the site was considered to be free *of M.bovis* the Movement Prohibition Notice was lifted 326 days following the death of the male llama. Approval under Directive 92/65 was reinstated 331 days following the death of the male llama allowing movements of susceptible animals into and out of the zoo to recommence.

This case study demonstrates the potential devastating impacts of infection with *M.bovis* both to the health and welfare of zoo animals but also the operation of the zoo as a conservation breeding centre. For almost a year this zoo was unable to import or export animals susceptible to *M.bovis*.

One of the many challenges of mitigating and investigating tuberculosis in zoos is the lack of validated tests. The ‘‘gold standard’’ of confirming an infection with the *M. tuberculosis* complex organisms is the isolation of the bacteria. The intra-dermal skin test, which is the accepted method of detection in tuberculosis in domestic hookstock, primates and man has not been standardized in many zoo mammals but is used widely (Kaandorp, 1998; Sternberg et al, 2002). Use of the intra-dermal skin test raises several issues. It requires double handling for injection and then reading of the test therefore requiring two anaesthetic procedures in many zoo animals. It detects only infection, not necessarily active disease and it has a low sensitivity, animals with advanced disease can give anergic responses to tuberculin (Bengis, 1999,) The low specificity of this test can cause false-negative test results in animals other than domestic hoofstock and nonhuman primates (Bengis 1999; Kaandorp, 1998) In some instances, even false-positive reactions can occur. Reindeer have been proven to regularly produce false positive reactions to the intra-dermal skin test (Palmer et al, 2006; Waters et al, 2005). These false positive results could lead to the unnecessary euthanasia of these animals if this species anomaly was not recognized. However, it has been determined that reindeer infected with *M.bovis* do reliably develop a robust response to the intra-dermal test and that false-negatives are rare (Palmer et al, 2006).

As in this case, inconclusive tests can occur. This happens when there is a small reaction to the tuberculin but under the thresholds sets for confirmation of a positive response (Sternberg et al, 2002). In this case the thresholds were set by the veterinary

authorities with a positive test being described as ‘an increase in skin thickness at the site of injection of PPD *M.bovis* by more than 2mm above the amount of increase at the site in injection with PPD *M.avium*. Inconclusive tests can be caused by incorrect injection of the antigens, incorrect reading of the test or abnormal immune reactions for example in young animals with maternal antibodies. In these cases the animals are retested at a defined interval following the initial test.

The camelids have proven to be especially problematic to reliably test for tuberculosis. The intra-dermal skin test has been demonstrated to have a sensitivity of only 14% in llama. Twomey and others (2010) identified seven animals, out of a cohort of 70 animals that tested negative for tuberculosis by intra-dermal skin test, but were confirmed to have the disease by confirmatory post-mortem examination within one to two months. Therefore confirming that, at least some of them, will have been infected with *M.bovis* at the time of the skin test.

In this case the male llama was definitely infected at the time of the initial routine skin test as he was examined by post-mortem that confirmed infection only 19 days later. Anergy to tuberculin when an infected animal fails to give a measurable hypersensitivity cutaneous response is a potential cause of a false-negative result but has never been proven in South American camelids (Twomey et al, 2010).

The lateral-flow rapid test VetTB STAT-PAK is a serological test that has been used widely in domestic and zoo animals (Lyashchenko et al, 2008). This test has the advantage that it only requires the collection of a single blood sample. In zoo animals it has been used where the risk of two anaesthetic procedures in a short period of time is considered to be high. In this case the RT was used on the Bacterian camels, which were unhanded and therefore would have required anaethetising for effective intra-dermal skin testing. The sensitivity and specificity of the rapid test in Bactrian camels is unknown but during investigations of a *M.bovis* outbreak in a racing herd of dromedary camels, the rapid test accurately detected all three confirmed infected camels out of the 55 tested with no false positive results (Wernery et al, 2007).

Again South American camelids are the exception, Twomey and others (2010) found a high rate of false positives with only 10 animals out of 54 testing positive to

tuberculosis by the RT being confirmed to be infected with *M.bovis* at post-mortem examination. The RT is not specific to *M.bovis* and so the results could be caused by infections with other mycobacterial agents but no evidence of this was found. The most appropriate testing regime that should have been used initially for this llama is a combination of intra-dermal skin test and serological testing as described by Bezos et al (2013). Preventative veterinary medicine best practice indicates that the llama should have been tested for tuberculosis prior to import as this outbreak and its consequences would have been prevented by the disease being detected at this stage (BIAZA, 2008). However, this is not required by either tuberculosis legislation or EC Directive 92/65. Balai approved premises are required to have a general disease surveillance programme and post import isolation process in place, both of which were complied with. The zoo should review its standard disease prevention measure and surveillance programme in light of this outbreak.

With the difficulties of handling, restraint and potential anaesthetic procedures combined with the challenges of reliably testing the animals for *M.bovis* a risk based process for undertaking the testing regime was required. This attempted to avoid testing animals where the risk of infection was considered low and there was the possibility of negative impacts on the health and welfare of the animals by undertaking the procedure. These risks could be further mitigated by the choice of the test chosen as in the case of the Bactrian camels.

By applying the risk based criteria the number of animals that required testing was considerably reduced and the process eliminated many zoo species where interpretation of the test results is not standardized and therefore interpretation difficult. The risk-based procedure had the unforeseen advantage that the highest risk species were primarily domestic species from the zoo's children's farm. Diagnosis of *M.bovis* in domestic species has been standardized and specific protocols and test interpretations have been defined.

In this case the zoo worked effectively with local environmental health officers to ensure that the potential risks humans were being addressed appropriately through biosecurity, disinfection, protective clothing and equipment and access restrictions.

This avoided any adverse impact on the zoos visitors and allowed the zoo to operate during the disease incident.

Close co-operation, collaboration and communication with the government veterinary authorities was essential for the successful resolution of this disease incident. The control of *M.bovis* on infected premises is defined in legislation written primarily for domestic commercial farms and therefore its application in zoos and non-domestic animals can be problematic primarily by interpretation of diagnostic testing. The risk based testing regime was defined by the zoo and the veterinary authorities working in collaboration, following discussion, inspections of working practice and assessments of operating procedures to define transmission risks. This resulted in an evidence-based investigation which was proportional and effective. Further, by having defined testing regimes and defined test interpretations even further prolonged restrictions on the zoo premises were avoided.

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Chapter 8. Disease Risk Analysis for Decision Making in Ex Situ Conservation Programmes. The Use of Risk Analysis Methodology to Generate Evidence Based Decision Making in Zoo Animal Disease Management – Using Simian Immunodeficiency Virus (SIV) in De Brazza Monkeys *(Cercopithecus neglectus)* as a Model.

8.1 Authorship Statement

Dr F Schmidt is a primate virologist and provided technical input and reviewed the virological component of this paper. The risk decision tree and associated management decisions were developed soley by myself.

8.2 Introduction to published paper

In this paper by Hartley & Schmidt, (2013) the principles of risk assessment are applied to managing the risks associated with simian immunodeficiency virus (SIV) to both humans and other primates in the European conservation programme for De Brazza monkeys *(Cercopithecus neglectus).*

As explained in the critique in Chapter 3 (Hartley & Sainsbury, 2017), the potential impacts of disease on wildlife conservation initiatives are well recognised, particularly when working with threatened populations in situ or undertaking conservation interventions to reintroduce or translocate endangered species.

Disease can also be a significant risk to ex situ conservation programmes which have no in situ component but still involve translocation, transportations and captive breeding involving multiple zoos (Miller, 2007). Although these disease risks have been recognised too there has been little focus on identifying and applying tools to analyse disease risks and modifying programme management in response to the findings (Pullin, Knight, Stone, & Charman, 2004; Sutherland, Pullin, Dolman, & Knight, 2004). Due to lack of evidence, decisions regarding disease risks in

conservation programmes are based on opinion or secondary sources (Sutherland et al., 2004). Often a ‘zero-risk’ approach is taken which impedes animal transfers, restricts demographic or genetic population management or results in euthanasia of animals infected with disease (Miller, 2007).

There have been attempts to develop a broad and unified set of processes and approaches to managing disease risks in conservation. Although these are intended to include risks to ex situ programmes the specific needs of these are not well described, demonstrated or implemented. In both key publications in the field only 1 example out of 16 provided involved an ex situ programme with no in situ component (Jakob-Hoff et al., 2014; Miller, 2007). There are few, if any peer reviewed papers describing the use of risk assessment to manage disease in ex situ conservation programmes in contrast to the expanding literature in the field involving in situ disease risks or disease risk in conservation interventions. This paper contributes to the field and has been used as the basis to develop further work on Simian Lymphotrophic Virus and Herpes B virus in primates in conservation programmes.

Viral pathogens of nonhuman primates are recognised as a potential zoonotic risk to humans which can result in high mortality (Travis, Hungerford, Engel, & Jones-Engel, 2006). However due to significant species specific variation, lack of empirical data and poor understanding of disease transmission, reservoirs and susceptibility decision making for disease prevention and control is problematic (Travis et al., 2006). Recent research has prioritised humans with the highest exposure to primates including consumers of primate bush-meat (Aghokeng et al., 2010; Peeters et al., 2002; Wolfe et al., 2004), visitors to ‘monkey temples’ in Asia (Engel et al., 2006; Fuentes, Shaw, & Cortes, 2007) and technicians working in research laboratories with nonhuman primates (Khabbaz et al., 1994; Sotir et al., 1997; Switzer et al., 2004; Weigler, Di Giacomo, & Alexander, 2005). Preliminary work has been undertaken on the occupational risks for zoo keepers but these have been serosurveillance studies or reviews rather than risk assessments (Kalter, 1989; Murphy et al., 2006; Roberts, 1995; Sandstrom et al., 2000). The paper in this chapter assesses the risk posed by SIV to zoo visitors, zoo staff, the individual primates and the primate population in the conservation breeding programme therefore giving a comprehensive perspective on the disease.

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8.4 Published paper

The Use of Risk Analysis Methodology to Generate Evidence Based Decision Making in Zoo Animal Disease Management – Using Simian Immunodeficiency Virus (SIV) in De Brazza Monkeys *(Cercopithecus neglectus)* as a Model.

M Hartley and F Schmidt

Abstract

Difficult decisions regarding the management of disease in zoo animals are faced routinely. These may have a significant impact on the individual animal or a population of animals and therefore the best available evidence must be used. However, in zoos there are many situations where there is a lack of peer-reviewed papers or significant uncertainty, controversy or confusion means that decision-making is hindered. This paper demonstrates how qualitative risk analysis techniques can be used to aide decision-making in circumstances where there is a lack of other evidence. Simian Immunodeficiency Virus in the De Brazza Monkey *(Cercopithecus neglectus)* has been diagnosed in the European population. Risk analysis was used to generate management guidelines to address the potential risks to other De Brazza monkeys, other primates and humans.

Introduction

Risk is the likelihood that a hazard will cause its effects, together with a measure of its impact (MacDiarmid & Pharo, 1997). Risk assessment is a tool intended to provide decision makers with an objective, repeatable and documented assessment of the risks posed by a particular course of action (MacDiarmid & Pharo, 1997). It is a tool now routinely used to guide policy making and disease control planning by

governments and international organisations such as the OIE (World Organisation for Animal Health). Risk assessment is intended to answer the questions:

- What can go wrong ?
- How likely is it to go wrong ?
- What would be the consequences of it going wrong ?
- What can be done to reduce the likelihood or the consequences of its going wrong?

This technique is rarely used to aide decision making in managed zoo captive breeding programmes. Risk assessment has significant potential to support Taxon Advisory Groups to formulate evidence based policies for issues where there is an element of uncertainty, confusion or controversy, as this technique is designed to present fully information in a structured and transparent way. It is particularly useful as qualitative rather than quantitative techniques can be used where numerical or statistical data is not available or is of limited value, due to small population sizes, for example.

Simian Immunodeficiency Viruses (SIV) are lentiviruses, which infect a wide variety of primates species (Ohta et al, 1988). Cases of SIV infection were diagnosed in De Brazza monkeys *(Cercopithecus neglectus)* (Bibollet-Ruche et al, 2004). There was considerable concern about the risks these animals posed to other primates and humans thus requiring policies to be developed for the management of these individual animals and the European Studbook (ESB) population as a whole.

This paper describes how risk assessment techniques were used to develop guidelines for the management of SIV in De Brazza monkeys in European Zoos.

Materials and Methods

There are a number of approaches to risk analysis, perhaps the most widely used and flexible is the OIE Risk Analysis Framework (1994). This is composed of four steps, Hazard identification, Risk Assessment, Risk Management and Risk Communication.

The Risk Assessment process is constructed using the following steps:

- Define the unwanted outcomes and the relevant risk questions.
- Clarify the steps, which are necessary to get from the hazard to the defined unwanted outcomes. This is usually achieved by producing a 'risk pathway'.
- Collect the information necessary to estimate the probability of each event in the pathway.
- Assess the risk

Risk management is the process by which the risk manager uses the results of the risk assessment, balanced with the 'level of acceptable risk' to determine the risk mitigation measures to be put into place. Levels of acceptable risk are value-based and affected by many factors including costs, culture and perceptions and will differ between different groups of those who are likely to be affected by the risk.

Risk communication is the exchange of information between risk managers, risk assessors and stakeholders during the development of the risk assessment and certainly before the policy is finalised. This often includes a peer-review process by experts both in risk assessment techniques to review the methodology and experts in the hazard that is being assessed. This is vital, to ensure acceptance of the risk assessment and implementation of the resulting decisions guided by it.

Results

Hazard Identification

The first stage in the process is the hazard identification, which determines the hazard(s) which are to be assessed. In this case SIV virus infection in De Brazza Monkeys is the hazard of concern.

Simian Immunodeficiency Viruses (SIV) are primate lentiviruses, which infect a wide variety of non-human primates species in sub-Saharan Africa. The evolution of the lentiviruses is very complex but there is some evidence to suggest that the viruses are ancient and co-evolved with specific species (Allan et al, 1990; Beer et al, 1999; Hirsch & Johnson, 1994). The virus that naturally infects the specific species causes lifelong unapparent infection but not clinical disease. However there is significant evidence of

multiple cross species infections (Ohta et al, 1988). In most instances these infections do not cause clinical disease but can on occasion result in immunosuppression, meningioencephalitis and lymphoproliferative disease.

The De Brazza monkey is naturally infected with its own SIV virus SIVdeb which is very distinct from other guenon SIV viruses (Bibollet-Ruche et al, 2004). It is non-pathogenic to De Brazza monkeys. Research suggests that up to 30% of this species are infected in the wild (Peeters et al, 2002).

Risk Questions

The next stage in the process is to determine the risk questions. In this study the risk questions are:

1. What is the risk that an SIV infected De Brazza monkey will transmit the virus to another De Brazza Monkey ?

2. What is the risk that an SIV infected Debrazza monkey will transmit the virus to another primate that is housed in the zoo ?

3. What is the risk that an SIV infected De Brazza monkey will transmit the virus to a human ? (either a keeper or zoo visitor).

Risk Pathways

The next stage is to develop the risk pathways for the two risk questions. These can be seen in Figures 1 and 2 respectively.

Risk Assessment

The risk assessment uses the risk terminology as shown in Table 1.

Risk Terminology

Term	Definition
Likelihood	Probability; the state or fact of being likely
Likely	Probable; such as well might happen or be true; to be reasonably expected
Negligible	So rare that it does not merit to be considered;
Very low	Very rare but cannot be excluded;
Low	Rare but does occur;
Medium	Occurs regularly;
High	Occurs very often.

Uncertainty is categorised as shown in Table 2.

Uncertainty Definitions

Low	Solid and complete data available; strong evidence provided in multiple references; authors report similar conclusions;
Medium	Some but no complete data available; evidence provided in small number of references; authors report conclusions that vary from one another;
High	Scarce or no data available; evidence not provided in references but rather in unpublished reports or based on observations, or personal communication; authors report conclusions that vary considerably between them.

<u>Risk Questions 1 and 2</u>

The risk pathway is broken down into its components and the risk for each step is assessed.

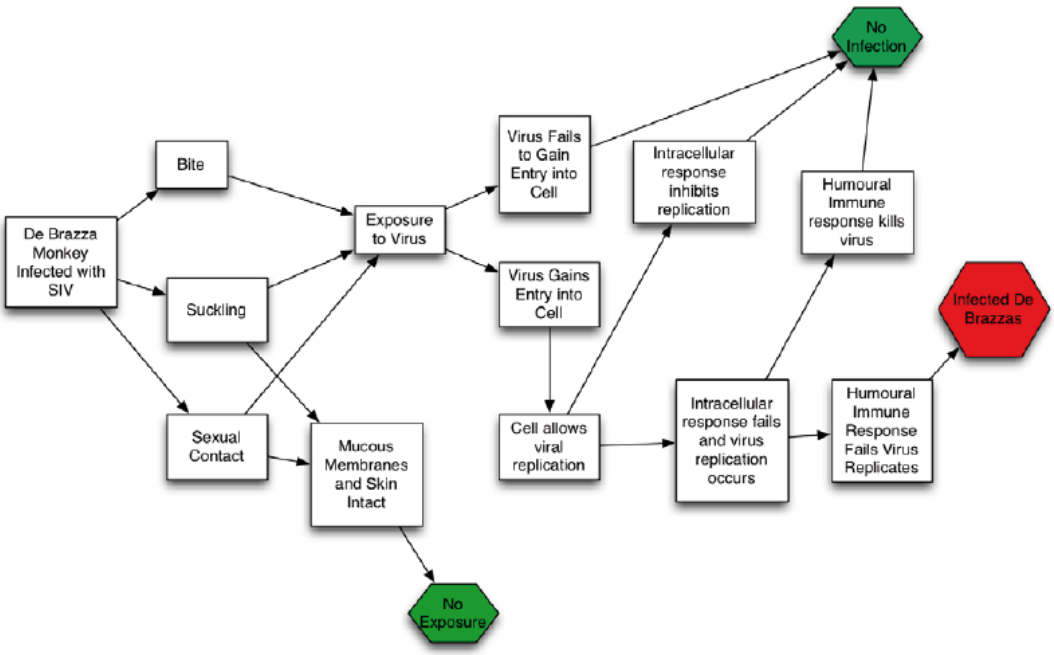

Figure 1. The risk scenario tree – the pathway of transmission between an infected De Brazza's monkey and an uninfected animal.

The virus is primarily transmitted horizontally through bite wounds and less commonly through sexual contact and breast milk. Indeed the virus can rarely be isolated from semen, cervical secretions and breast milk (CDC, 1998). This does vary between species, with research suggesting that SIV in sooty mangabeys is definitely spread sexually and whilst less so in Mandrills (George-Coubert et al, 1996). No experimental infections to further investigate transmission of SIV in De Brazza monkeys have taken place .

Once the virus is transmitted to the new host it must enter the cells via cell receptors. The host's immune system will try and prevent this. There is evidence that intra-species and inter-species exposure does occur but an effective immune response prevents infection as animals have been found to be serologically positive for SIV infection but not infected with the virus (Vandewoude et al, 2010).

To infect the animal the virus must successfully enter the cells and interact with cell organelle in order to replicate (Vandewoude et al, 2010). As the SIV viruses are very species specific it is likely that there will be incompatibility and the virus will not be able to replicate and therefore not be able to infect the animal.

This is summarised in Table 3.

Stage in Risk Pathway	Bite Wound Sucking Sexual Contact	Virus Infects Cell	Virus replicates in Cell	Virus causes active disease in another primate.
Mitigating Actions	Avoid conflict in groups so that aggression is low. Hand raise infants of infected mothers. Do not allow infected monkeys to mate with uninfected monkeys.	Post exposure prophylaxis.	None possible but the SIV virus are very species specific and so there is likely to be cell receptor incompatibility.	
Risk	Medium	Medium	Medium in other De Brazzas. Very Low in other primates	Low
Uncertainty	Medium	Medium	Medium	Low

Overall Risk Assessment = Low to Medium Risk with Medium uncertainty.

Risk Question 3

A study of people with occupational exposure to primates was conducted by the USA

Centers for Disease Control and Prevention. 3,000 samples from people potentially exposed to SIV were tested. Only two demonstrated antibodies cross reactive to SIV, a prevalence of less than 1%. One of these people handled known (experimentally) SIV infected material without gloves whilst having a severe dermatitis of the hands and forearms. The second person had suffered from a needle stick injury whilst handling known experimentally infected blood. Both of these people had virtually undetectable levels of virus and this explains the lack of AIDS like symptoms as a high circulating viral load is required for disease and transmission in HIV infected humans. Evidence of SIV infection in zoo keepers has not been reported (Weston Murphy et al, 2006).

Epidemiologic surveys of 1800 persons from nine villages in Cameroon suggested very high (>60%) exposure to nonhuman primate blood and body fluids and demonstrated that 1% of exposed individuals were seropositive for SIV of three different nonhuman primate origins (Wolfe et al., 2004). Despite the fact that these events clearly demonstrate that human-primate contact occurs commonly, and can result in nonhuman primate to human retroviral transmissions, human exposure to SIVs resulting in patent infections has been extremely rare. Therefore, exposure of humans to SIVs does not *a priori* result in successful cross-species infection; seropositivity merely demonstrates exposure to SIV and a subsequent immune reaction. It does not demonstrate infection.

Cross species infection from the natural host to other species can occur and can result in pathological disease. Cross species transmission of the specific Chimpanzee and Sooty Mangabey SIV viruses to humans has been linked to the origin of the HIV-1 and HIV-2 virus respectively. It is thought that the SIVs entered human cells, underwent genetic changes, which then allowed human-to-human transmission. This is supported by the fact that humans in Africa have been exposed for centuries to SIVs and yet the HIV epidemic has only apparently emerged in the second half of the last century, which suggests that some other factor influenced the virus. This suggests that viral cross –species transmission is in itself not the only factor required for development of pathological disease (Wolfe et al, 2004).

Despite the large exposure of humans to SIV-infected primates in central and west Africa, through consumption of bushmeat, extensive molecular epidemiological studies have shown only 10 cross-species transmission events during the last century only four of these resulted in epidemic transmission (Apetrei et al, 2004). Experimental cross species infection of SIVs in different species of primates has shown that in many cases the virus is harmless or cleared by the new hosts immune system

There are over 40 SIV species specific virus and only those from chimpanzees (SIVcpz) and sooty managabeys (SIVsm) have been shown to be associated with HIV. Indeed SIVdeb is one of the most genetically distinct viruses and is not similar to these two SIV viruses (Apetrei et al, 2004). The general experimental approach to determine this is to try and grow virus in human cells (human peripheral blood mononuclear cells, PBMCs) *in vitro.* Although many SIV viruses have been shown to grow in PBMCs most of the cercopithecine SIV viruses do not grow in human PBMCs (Apetrei et al, 2004; Grimm et al, 2003). None of the cercopithecine SIV viruses have been identified in humans (Apetrei et al, 2004).

Table 4 – Risk Pathway for Human Exposure to De Brazza monkey SIV virus

Stage in Risk Pathway	Bite Wound or Mucus Membrane Exposure	Virus Infects Cell	Virus replicates in Cell	Virus causes active disease in human
Mitigating Action	Handling Precautions, Gloves, Goggles, Face Mask, Washing hands, appropriate wound management	Post Exposure Prophylaxis	Cells do not have correct receptors or cellular function to allow virus to replicate	None
Further Evidence		In both occupational at risk workers and bush meat hunters seroprevalence was less than 1%. Infection in Zoo keepers has not been reported.	SIVdeb virus do not replicate in human PMBCs.	Despite regular and widespread exposure cross for centuries only 10 incidences of cross- species infection have been identified and only 4 of these have resulted in human disease.
Risk	Low	Negligible	Negligible	Very Low
Uncertainty	Low	Low	Low	Low

Overall Risk Assessment = Very Low to Negligible with Low Uncertainty.

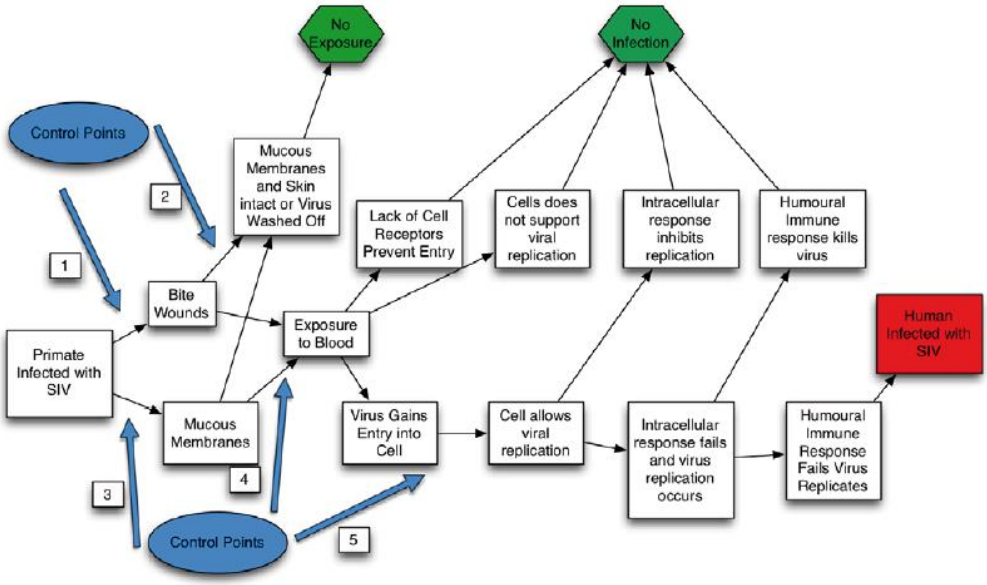

Figure 2. Transmission pathway from SIV-infected De Brazza's monkey to a human.

Risk Management

By using the risk pathways it is possible to identify potential control points at which the risk pathway can be blocked and the likelihood of the pathway being completed reduced.

In both pathways there are two control points; the first is preventing transmission and the second is preventing the virus from infecting cells. Once the virus has entered the cell there is little practical intervention possible to prevent infection.

There are several ways that transmission of SIV from an infected De Brazza monkey could be prevented. SIV infected animals could be euthanased or they could be housed individually in isolation facilities. In order to prevent infection of young born to SIV infected mothers infected animals could be contracepted or the young removed for handraising. Other options include managing SIV infected monkeys in groups composed only of infected animals and enforcing management guidelines designed to reduce aggression and conflict in De Brazza monkey groups with known infected animals.

The second control point is attempting to prevent infection in an animal exposed to the virus through the use of prophylactic drugs. This has not been attempted widely in naturally occurring exposure but has been effective in experimental infections.

Transmission to humans can be prevented through the use of protective clothing and management practices, which reduce the risk of animal bites and bodily fluid transfer. Following a mucus membrane or bite wound exposure copious lavage with chlorhexidine which is virostatic can be effective. Post Exposure Prophylaxis with anti-retroviral drugs may be indicated following potential exposure. Medical intervention should be sought. (Weston Murphy et al, 2006).

Risk Communication

This risk assessment was reviewed in three ways as part of risk communication. The paper was reviewed by an expert in SIV to ensure technical and scientific completion and accuracy. The paper was also reviewed by members of the Old World Monkey Taxon Advisory Group and presented to this group in a formal meeting for ratification.

Risk Mitigation and Discussion

This risk assessment allowed structured and objective evidence base to be presented to the European Association of Zoos and Aquaria (EAZA) Old World Monkey Taxon Advisory Group (TAG) for development of a management strategy for SIV infection in the European Studbook population of De Brazza monkeys. The risks identified need to be balanced with the requirement to maintain and increase a genetically sound population of this species in European zoos.

The first decision that was made was that it is essential to know which animals in the population are SIV positive and which are not. This allows the zoos to be able to implement the management protocols devised and actively manage the low but potential risks to humans and other species of primates sharing mixed exhibits with De Brazza Monkeys. Accordingly the TAG has advised that De Brazza Monkeys of SIV positive or unknown status should not be housed in mixed exhibits with other primate species.

The risk assessment provides evidence to allow the following advice to be provided to keepers working with De Brazza monkeys infected with SIV. The majority of these should be in use for routine contact with non-human primates in a zoo environment.

The risk of transmission from urine and faeces is negligible and SIV virus is susceptible to household bleach and disinfectants, which should be therefore used routinely for general cleansing.

Blood is the main risk to humans. As with all primates, latex gloves should be used when handing De Brazza monkeys. Unknown status or SIV positive De Brazzas should not be handled when conscious to avoid biting injuries and should not be netted but should be darted or a put in a crush cage and then examined under anaesthesia only. Should biting injuries occur they should be immediately, thoroughly washed and lavaged with chlorhexidine. During blood collection or other invasive procedures; on unknown status or SIV positive animals, goggles, gloves and face-masks should be worn to prevent mucous membrane contamination. If mucous membranes (eyes, mouth, nose, ears) be contaminated by SIV infected primate bodily fluids the area should be immediately washed with chlorhexidine.

The more challenging management issue is to decide if the management of the De Brazza Monkey ESB should be changed in light of SIV status when SIV in De Brazza monkeys is a naturally occurring infection and is non-pathogenic. However due to perceptions and misunderstanding of the risks some zoos are reluctant to hold SIV infected animals and in some collections SIV status has contributed to a decision to euthanase animals (Redrobe, Pers.Comm). There is also a moral quandary of placing an animal at risk of an infectious disease, albeit a non-pathogenic disease by knowingly moving into a group infected with SIV.

It was decided to collect further information on the status of the current ESB population and to make management decisions which avoided increasing the number of SIV infected animals by not introducing SIV infected animals to groups that were not infected or of unknown status.

Testing for SIV in primates is well established. However there have been some problems with interpretation of the results of tests undertaken by different laboratories as the test have differing sensitivities (ability to detect a positive result). This has resulted in animals previously testing negative to test positive when tested by a different laboratory. It is important to remember that once animals test positive they cannot revert to being negative. If an animal tests negative if could have been recently infected and the virus has not yet replicated to detectable levels. As the amount of virus in the animal is so low it will not yet be able transmit disease. This animal can be considered negative but at some undeterminable point will test positive when virus reaches detectable levels. This is rare as all the tests can detect virus at very low levels. If an animal tests negative and then at a later date tests positive it has been infected by the virus in the intervening period and the animals which it has been in contact with should be tested for SIV. In order to ensure consistency and expert interpretation of the results obtained the De Brazza monkey ESB has recommended using a single laboratory for all testing.

It was decided to undertake testing strategically and focus on groups of monkeys that were involved in movement transactions. This is for two reasons; firstly that these animals have the greatest potential to change the infected status of a group and secondly that the potential conflict during introductions increases the risk of transmission.

Therefore the ESB instructed that when a movement recommendation has been made both the animal that is being sent to the new zoo and the entire group where the animal is destined for should be tested for SIV. In this way we can ensure that a SIV positive animal is not moved into a SIV negative group or vice versa. Zoos are also being encouraged to submit samples opportunistically.

It was decided that any animal that did test positive for SIV should not be euthanased but that groups of know positive animals would be established so that these animals could continue to play an important and full role in the ESB. It is important not to presume that offspring born to SIV positive parents are also positive so using contraceptives in infected females was not considered appropriate.

It was also decided that due to the non-pathogenic nature of the virus, stable family groups do not need to be broken up if one of the animals tests positive. This positive result has no implications for the health of the group and indeed, an increased risk of SIV transmission will be caused by disrupting the group and increasing the likelihood of fighting. By disrupting established breeding groups it was felt that the long-term viability of the ESB would be threatened.

The additional evidence obtained from the risk mitigation processes described above will be fed back into the risk assessment process. Regular review of the risk assessment in light of new information and evidence ensures that the management decisions are still appropriate.

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Chapter 9. The Use of Risk Analysis Beyond Disease. Assessing Risk Factors for Reproductive Failure and Associated Welfare Impacts in Elephants in European Zoos.

9.1 Introduction to published paper

The study reported in this paper (Hartley, 2016) is one of the first applications of risk assessment techniques, integrating multiple sources of evidence, to investigate welfare in a zoo environment. It builds on previous papers in this thesis by using original data collected from a survey which is reported by Hartley & Stanley, (2016). It is an example of a novel epidemiological approach to animal welfare and management studies advocated in recent literature (Barber, 2009; Carlstead et al., 2013; Noordhuizen & Frankena, 1999; Rushen, 2003).

Recommendations for best practice in zoos are often based on 'current' practice', expert opinion or anecdote rather than empirical evidence (Melfi, Bowkett, Plowman, & Pullen, 2005). One of the reasons for this is that the study of animal management and welfare in zoos is problematic from a methodological perspective (Carlstead, Mench, Meehan, & Brown, 2013; Melfi, 2009). The number of animals available at one institution is limited. A multitude of environmental and management confounding factors impede standardised experimental design. Very little is known about the biology of many species and indicators of good or bad welfare are poorly understood (Melfi, 2009). In order to identify gaps in knowledge and enhance the welfare of zoo animals, adoption of multi-disciplinary techniques beyond controlled experimental methods have been proposed as a way to develop evidence-based management decision making (Carlstead et al., 2013).

Evidence based frameworks are well suited to zoo management decision making because they do not exclude any source of evidence (Melfi, 2009). Expert opinion and practitioners' experience can be utilised to collate and interpret evidence and the process assesses reliability of the evidence during integration into the output. In addition the impact of decisions is monitored to facilitate adaptive management and

feedback into an ongoing process of improvements (Barber, 2009; Sutherland, Pullin, Dolman, & Knight, 2004).

Current literature refers to 'epidemiological approaches' but fundamentally they describe the application of disease risk assessment techniques to animal welfare and management (Barber, 2009; Carlstead et al., 2013; Noordhuizen & Frankena, 1999; Rushen, 2003). Epidemiological approaches have been proposed to study multifactorial animal welfare and management problems (Rushen, 2003). Epidemiological studies are recognised as an effective way to identify the interactions of the environment and management factors which can lead to welfare problems and identify areas for improvement (Barber, 2009; Carlstead et al., 2013). This is confirmed in the paper in this chapter.

Epidemiological approaches use welfare indicators, often determined through consultation with experts, to provide key information about the care of the species. These may include mortality, morbidity or fecundity data obtained from zoo record systems which include a defined zoo population (Fidgett, Pullen, & Brunger, 2008). The patterns of the welfare indicators within the population and the prevalence of factors which positively and negatively influence welfare provide potential explanations for the population parameter data collected (Barber, 2009). Although risk assessment can help to identify key risk factors it cannot determine definite causality which should be investigated in hypothesis driven research (Barber, 2009).

It is only recently that veterinary epidemiologists and animal welfare scientists have begun working together to apply epidemiological approaches to animal welfare problems in captive environments (Carlstead et al., 2013). It has been recognised at the European level that there is a need to develop a formal approach to risk analysis for animal welfare (European Food Safety, 2006a) which was realised by the assessment of the welfare of intensively reared calves (European Food Safety, 2006b). A critique of this specific assessment identifies that, whilst a useful approach, improvements in hazard definitions, collation of expert opinion, assessment of uncertainty and transparency of underlying data would increase robustness (Bracke, Edwards, Engel, Buist, & Algers, 2008). The paper in this chapter (Hartley, 2016) has attempted to address these criticisms by further developing risk assessment

methodology for the study of animal welfare. Further critique of risk assessment as a methodology is provided in Chapter 10.

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9.3 Published paper

Assessing Risk Factors for Reproductive Failure and Associated Welfare Impacts in Elephants in European Zoos.

M Hartley

Abstract

Reproductive failure in elephants is thought to be caused or influenced by a range of factors such as obesity, infectious disease, husbandry, facilities, stress, behaviour, maternal experience, herd size and social grouping. Due to the low reproductive activity of the small zoo elephant population, scientific study into the relative importance of these factors is limited.

This study takes an epidemiological approach using risk analysis methodologies to collate information from expert opinion, data set analysis and a targeted questionnaire to identify and assess a range of physical, behavioural and husbandry based risk factors, which may affect reproductive success in elephants housed in European zoos.

Much of our knowledge on reproduction in zoo elephant populations originates from North America where there are significant differences in herd structure, management practices, climate and mean age with the European zoo elephant population. By combining multiple sources of evidence including a large survey of reproduction in the European elephant population and eliciting expert opinion from scientists, zoo managers, veterinarians and keepers working with European zoo elephants in a structured, transparent and scientifically recognised process it has been possible to identify the most important causes of reproductive failure and assess the influence of a range of potential confounding factors.

Important causes of reproductive failure included lack of access to a compatible bull, herd instability and compatibility, lack of allomothering or maternal experience,

management practices at parturition and the impact of Elephant Endotheliotropic Herpes Virus.

This work is to be used in the development of evidence-based elephant management and welfare recommendations and highlights priority areas for further research.

Introduction.

Successful reproduction in captive elephants is not necessarily an indication of high welfare standards but investigating reproductive failure could identify causes of compromised welfare. Dystocia, stillbirth, reproductive pathology and neonatal morbidity and mortality have all been reported in zoo elephants. Many causative and contributing factors such as obesity, infectious disease, husbandry, facilities, stress, behaviour, herd size and social grouping have been proposed, but due to the low reproductive activity of a small population scientific study into the relative importance of these factors is limited.

Reproductive and maternal behaviour in elephants promotes positive welfare by encouraging social interaction, herd cohesion and an increased repertoire of behaviours including mating and maternal behaviours. Identification of the most significant influences on reproduction would enable zoos to mitigate against reproductive failure and associated negative welfare or to improve opportunity for reproduction and promote the positive impacts of reproduction.

There are several studies examining specific factors associated with reproduction such as group size (Rees, 2009), acyclicity (Brown et al, 2004: Proctor et al, 2010), infant mortality (Taylor & Poole, 1998; Mar et al, 2012) and dystocia (Flugger et al, 2001; Murray et al, 1996)

There have been a number of studies using statistical analysis of zoo studbook data to assess reproductive failure (Dale, 2010) and then compare this to timber camp elephants (Schmidt & Mar, 1996: Taylor & Poole, 1998; Hayward et al, 2014) and timber camp elephants and wild African elephants (Clubb et al, 2008; Clubb et al, 2009). The results were then used to assess welfare of zoo elephants using infant mortality and fecundity as indicators. These studies found that fecundity and

reproductive life-span was lower and still-birth rate, infanticide and acyclicity higher in zoo elephants and proposed obesity and stress as potential causative factors.

Mason & Veasey (2010) built on these studies to use population level indices such as fecundity, acyclity stillbirths and infant mortality to propose links to assessment of welfare and the use of these factors as welfare indices. They concluded that low fecundity, premature reproductive senescence, acyclicity and high stillbirths rates could be caused by stress or other forms of poor welfare. However they also accepted that management factors such as access to mates and inadequate reproductive experience could equally cause these population level effects.

Harris, Sherwin & Harris (2008) surveyed physical and husbandry conditions and gathered physiological and behavioural data relating to 77 elephants in 13 UK zoos. They proposed indicators of elephant welfare and calculated the prevalence of welfare outcomes. They then attempted to identify risk factors related to husbandry and housing using statistical analysis. This study did not assess reproduction, maternal behaviour or bull management and did not identify any welfare risk factors associated with these issues. The authors determined that, due to the very small sample sizes and the nature of the data, the statistical analysis used was not robust.

Clubb & Mason (2002) conducted a comprehensive study of European zoo elephant welfare through a review of published literature, secondary source materials and interviews with experts. A range of statistical data regarding infant mortality and reproductive failures in both male and female elephants was produced and the authors proposed some causative reasons for these findings. Due to limited access to information on elephant management they were unable to link these findings with specific risk factors.

All of these studies combined assessment and analysis of both species of elephant in single studies despite it being recognised that the population demographics and management and training systems differ significantly between species. Additionally, it is appreciated that there are significant differences in elephant management between North American and European zoo populations and therefore it cannot be presumed that results of studies in one population can be directly applied to the other.

This study builds on previous work by utilising peer reviewed and grey literature, expert opinion and studbook data in combination with detailed elephant husbandry and management information and robust statistical correlation analysis. The specific differences between species and populations are addressed. Recommendations for changes to elephant management, which reflect the most significant risk factors identified are made.

This work is a qualitative risk analysis using standardised techniques to assess risk factors which result in negative welfare impact during reproductive activity in elephants housed in European zoos. It provides an evidence-based assessment of those factors, which influence the likelihood of a successful reproductive event, defined by the birth of a life calf that is maternally reared to independence. The analysis indicates which factors have a greater risk of leading to a negative outcome. This allows for management recommendations to be made regarding these factors and therefore to reduce the likelihood of negative reproduction associated events occurring. This can contribute to improving the welfare of elephants in captivity by implementing measures, which could reduce the risks of stillbirth, abortion, neonatal morbidity and mortality, maternal rejection and suboptimal social behaviour that have been associated with reproduction in captive elephants and identified as negative welfare indicators.

Materials and Methods

Epidemiology is the study of patterns in defined populations with the aim of understanding the prevalence of hazards and the risk factors associated with their occurrence. Once the factors have been identified, effective strategies can be developed to minimise those risks (Carlstead et al, 2014). Epidemiology is usually associated with the study of disease but is increasingly being applied to animal welfare studies including with elephants (Carlstead et al, 2014).

There are three approaches to collecting data for welfare epidemiological studies; surveying or interviewing people familiar with the subject population, analysis of pre-existing data collected or a different purpose and collecting data directly from the population under investigation. All three approaches were used in this study.

Risk analysis processes provide an objective, repeatable, transparent and documented assessment of the risks posed by a course of action or chain of decisions. Standardised techniques have been developed and are utilised to aid decision-making. It is a tool now routinely used to guide policy making and disease control by governments and international organisations such as the OIE (World Organisation for Animal Health) (Murray et al, 2004).

This technique has rarely been used to aid decision making in managed zoo captive breeding programmes (Hartley and Schmidt, 2013) but risk analysis has significant potential to support formulation of evidence based policies for issues where there is an element of uncertainty, confusion or controversy, as this technique is designed to present fully referenced information in a structured and transparent way. It is particularly useful as qualitative rather than quantitative techniques can be used where numerical or statistical data is not available or is of limited value.
Previous studies on reproduction in elephants have been hampered as they have depended on statistical analysis based on very small samples sizes. By using risk analysis this limitation can be managed so that evidence based recommendations to improve welfare can be made.

The OIE Risk Analysis Framework (Murray el, 2004) forms the basis of risk analysis systems used for a wide variety of disease outbreak scenarios. This framework was revised for use in this study but retains the fundamental concepts of risk analysis. A representation of this framework is shown in figure 1.

Figure 1: Simplified risk analysis framework used in this study based on the OIE Risk Analysis Framework (Murray et al, 2004).

Two hazards were defined, failure to conceive and failure to rear a calf to five years of age and so two separate but connected risk pathways were developed. These are shown in figures 2 and 3. These pathways define the processes experienced by a system (in this case a female elephant) in order for the hazard to occur. Defining these

steps allows specific evidence to be assessed independently and simplifies analysis of complex processes. Risk factors, which impact on the progression between the steps in the risk pathway are identified. This was achieved through a comprehensive peer-reviewed and grey literature search and outputs from an expert advice panel. This panel was composed of elephant keepers, zoo curators, managers, directors, scientists and veterinarians with experience of working with elephants. The group was asked to identify facility features, husbandry, health or management issues which they considered to impact on successful reproduction. The risk factors identified are shown on figures 2 and 3.

Figure 2: Risk Pathway showing Risk Factors for Failure of Elephant Conception.

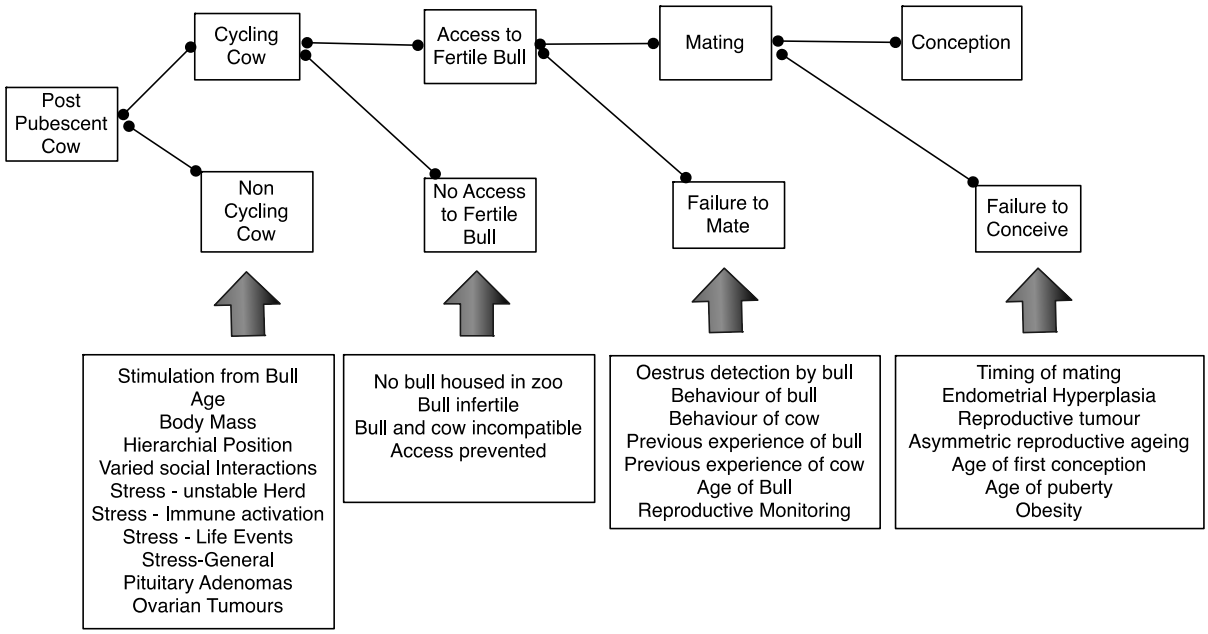
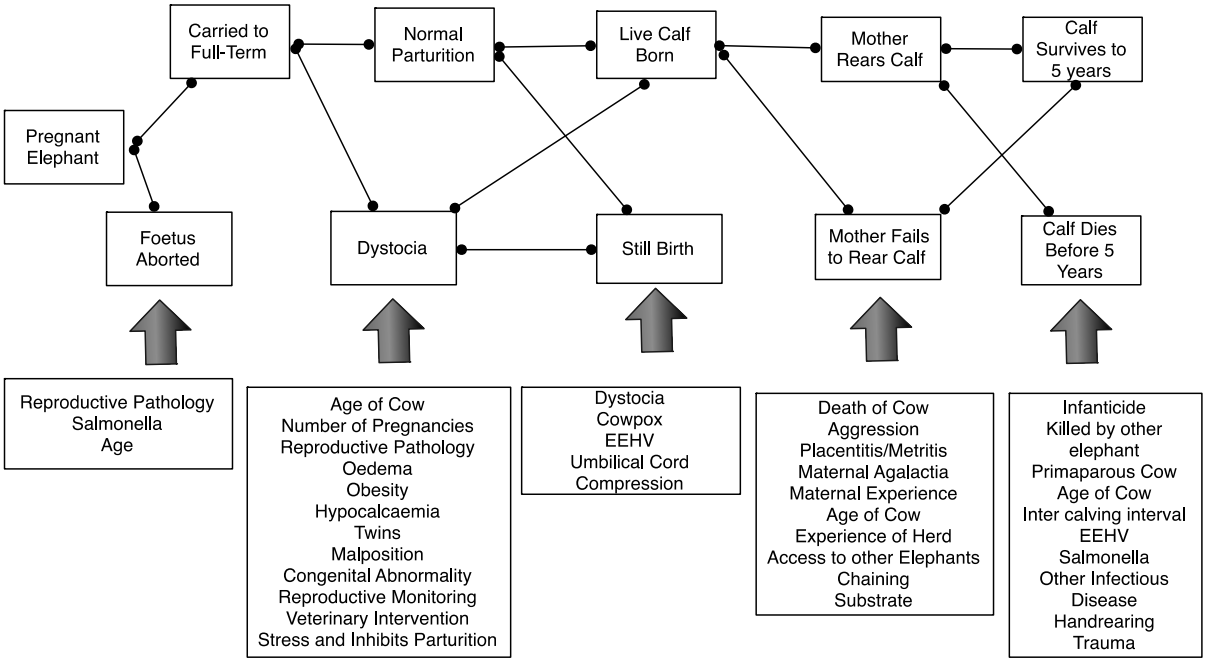


Figure 3: Risk Pathway from Conception to Rearing Calf to 5 Years Showing Risk Factors.



The risk assessment itself is an estimation of the probability of each step in the pathway occurring, this can be either quantitative where available or qualitative. The probability is estimated following analysis of available evidence.

The European studbooks for Asian Elephants (2011 edition) and African Elephants (2012 edition) updated with relevant unpublished annual reports were interrogated to investigate life histories of elephants and calculate reproductive parameters of interest such as age at birth. These studbooks contain demographic information, including births, deaths, parentage and transfers between holdings of elephants held in zoological institutions. These studbooks contained 984 Asian elephants dating back to 1830 and 475 African elephants dating back to 1865. The studbook data was used to assess the social and maternal histories of the current living female elephant population (259 Asian and 150 African) and to determine individuals to be included in two questionnaire surveys.

The first questionnaire was focused on investigating risk factors, which impacted on elephants conceiving. Three separate cohorts of elephants were identified of interest for this component of the study; those that had conceived previously but had not conceived in the past five years (the average inter-birth interval in captive Asian elephants has been determined to be 5 years (Mar et al, 2012); those elephants which had never conceived despite being housed at the same zoo as a proven bull for a

period of at least 12 months during its adult lifetime and those elephants which had never conceived but had never been housed with a proven bull. The distinction between the latter two cohorts of elephants allows for the fact that a cow may be completely fertile and able to conceive but has failed to do so because they have never been mated by a fertile bull.

Information regarding elephants that were reproductively active was not collected as these elephants are not currently being impacted by the risk factors under investigation and so would not contribute to identification of the most important risk factors, which require management actions. The questionnaire for each elephant was detailed and complex, requiring significant time and effort from zoo staff to complete and therefore a prioritised approach to requesting data was likely to have aided participation.

The second questionnaire was designed to collect information from the point of parturition to rearing the calf to the age of five years. The questionnaire was specific to each birth event recorded in the studbooks (and the 2013 Taxon report which supplements the studbook and adds information for the year 2012-3), therefore multiple questionnaires were completed concerning multiparous cows. This covered a period of 1992 – 2013.

Further explanation of the questionnaire and its results are reported in Hartley & Stanley (2016.

The risk assessment was constructed by combining the findings from the two questionnaires, interrogation of the studbook data and the peer reviewed literature for each risk factor and then qualitatively assessing the likelihood that the risk factor would have an impact on successful reproduction using the criteria defined in Table 1.

Table 1: Risk Definitions used in Risk Analysis

Term	**Definition**
Negligible	So rare that it does not merit to be considered;
Very low	Very rare but cannot be excluded;
Low	Rare but does occur;
Medium	Occurs regularly;
High	Occurs very often.

A further assessment on uncertainty was added to identify areas of weak, incomplete or conflicting evidence. In cases where all or the majority of sources of evidence; expert opinion, peer-reviewed and grey literature, studbook analysis and the results of the questionnaire support a similar risk assessment there was considered to be low uncertainty. If the survey findings presented were found to be statistically supported the factor was determined to have low uncertainty as a robust association had been found. Where the evidence sources conflicted or the questionnaire results were not found to be statistically significant uncertainty was considered to be medium or high.

Risk management is the process by which the risk manager uses the results of the risk assessment, balanced with the 'level of acceptable risk' and to determine the risk mitigation measures to be put into place. The levels of acceptable risk and therefore the extent of the mitigation measures will vary depending on resources, ethics, and other confounding factors.

Results

The tables below present the risk assessment and uncertainty rating for each stage in the risk pathways shown in figures 2 and 3. The peer reviewed papers, which include evidence relating to the risk factors and referred to using reference numbers from the citations list in this paper. The detailed results of the questionnaire are presented in an associated paper (Hartley and Stanley, 2016), an indication if the results supported the risk assessment is provided. The results are ranked from a high risk to a low risk.

Table 2a: Risk Assessment for the Impact of Identified Risk Factors on the Likelihood of Acyclicity in African Elephants in European Zoos.

Risk Factor	**Supported by Peer Reviewed Papers**	**Supported by Questionnaire Results**	**Risk Assessment**	**Uncertainty**
Older Age of Cow	5,20,22,47	Trend	High	Low
Less Access to Daylight	4,58,	Trend	High	High
Higher Hierarchial Position	20,22,47	No	Medium	Low
Lack of Change in Social Group	21,	Yes	Medium	Medium
Immune Activation Inflammatory Disease	3,6	No	Medium	Medium
Reproductive Tract Pathology	5,31,34	No	Medium	Medium
Obesity	21,	-	Medium	Medium
General Stress	10, 26, 47	-	Medium	High
Lack of Stimulation from Bull	21,44	Yes	Medium	High

Table 2b: Risk Assessment for the Impact of Identified Risk Factors on the Likelihood of Acyclicity in Asian Elephants in European Zoos.

Risk Factor	**Supported by Peer Reviewed Papers**	**Supported by Questionnaire Results**	**Risk Assessment**	**Uncertainty**
Less Access to Daylight	4,58	Trend	High	High
Obesity	21	-	Medium	Medium
General Stress	10,12,25,56	-	Medium	High
Lack of Stimulation from Bull	21,44	Yes	Medium	High
Lack of Change in Social Group	12, 17, 25, 56	No	Medium	Medium
Older Age of Cow	5,20,22,47	Trend	Medium	Medium
Higher Hierarchial Position	-	No	Low	Low
Immune Activation Inflammatory Disease	-	No	Low	Medium
Reproductive Tract Pathology	31,34	No	Low	Medium

Table 3a : Risk Assessment for the Impact of Identified Risk Factors on the Likelihood of African Elephants in European Zoos not having Access to a Bull.

Risk Factor	**Supported by Peer Reviewed Papers**	**Supported by Questionnaire Results**	**Risk Assessment**	**Uncertainty**
Cows not given access to bulls overnight	40,42	Yes	High	Low
Incompatible Behaviour	40,	Yes	High	Low
Access only given when in oestrus	40,45,60	Yes	Medium	Low
No Bull Housed	40,	Yes	Medium	Low

Table 3b : Risk Assessment for the Impact of Identified Risk Factors on the Likelihood of Asian Elephants in European Zoos not having Access to a Bull.

Risk Factor	**Supported by Peer Reviewed Papers**	**Supported by Questionnaire Results**	**Risk Assessment**	**Uncertainty**
Cows not given access to bulls overnight	40,42	Yes	High	Low
Access only given when in oestrus	40,	Yes	High	Low
Incompatible Behaviour	40,	Yes	High	Low
No Bull Housed	40,	Yes	Low	Low

Table 4a: Risk Assessment for the Impact of Identified Risk Factor on the Likelihood of African Elephants in European Zoos Failing to Mate.

Risk Factor	**Supported by Peer Reviewed Papers**	**Supported by Questionnaire Results**	**Supported by Studbook Evidence**	**Risk Assessment**	**Uncertainty**
Lack of Choice of Bull	44	-	Yes	High	Low
Young Age of Bull	44,	-	Yes	High	Low
Cow Refuses to Stand to be Mated	24	Yes	-	High	Low
Bull Refuses to Mate Cow	24	Yes	-	Medium	Low
Lack of Previous Experience of Bull	16,24	_	Yes	Medium	Low
Lack of Previous Experience of Cow	24	-	No	Low	Low

Table 4b: Risk Assessment for the Impact of Identified Risk Factor on the Likelihood of Asian Elephants in European Zoos Failing to Mate.

Risk Factor	**Supported by Peer Reviewed Papers**	**Supported by Questionnaire Results**	**Supported by Studbook Evidence**	**Risk Assessment**	**Uncertainty**
Lack of Choice of Bull	-	-	Yes	High	Low
Young Age of Bull	-	-	Yes	Medium	Low
Cow Refuses to Stand to be Mated	24	Yes	-	Medium	Low
Bull Refuses to Mate Cow	24,49,50	Yes	-	Medium	Low
Lack of Previous Experience of Cow	24,51	-	No	Medium	Low
Lack of Previous Experience of Bull	24,49,50	_	No	Low	Low

Table 5a: Risk Assessment for the Impact of Identified Risk Factors on the Likelihood of African Elephants in European Zoos Failing to Conceive.

Risk Factor	**Supported by Peer Reviewed Papers**	**Supported by Questionnaire Results**	**Supported by Studbook Evidence**	**Risk Assessment**	**Uncertainty**
Unproven Bull	32,33	-	Yes	High	Low
Reproductive Pathology	31,32,34	No	-	Low	Medium
Age of Cow	31	No	No	Low	Low
Young Age of Puberty	32,34	No	-	Low	Medium

Table 5b: Risk Assessment for the Impact of Identified Risk Factors on the Likelihood of Asian Elephants in European Zoos Failing to Conceive.

Risk Factor	**Supported by Peer Reviewed Papers**	**Supported by Questionnaire Results**	**Supported by Studbook Evidence**	**Risk Assessment**	**Uncertainty**
Reproductive Pathology	2,31,32,34,	No	-	Medium	Medium
Age of Cow	31, 60	No	Yes	Medium	Low
Young Age of Puberty	57	No	-	Medium/Low	Medium
Unproven Bull	32,33	-	No	Low	Low

Table 6a: Risk Assessment for the Impact of Identified Risk Factors on the Likelihood of Abortion in African Elephants in European Zoos.

Risk Factor	**Supported by Peer Reviewed Papers**	**Supported by Questionnaire Results**	**Risk Assessment**	**Uncertainty**
Stress	10	-	Low	High
Age of Cow	-	No	Very Low	Medium
Primiparous Cows	-	No	Very Low	Medium
Reproductive Pathology	-	No	Very Low	Medium
Salmonella	15	Yes (1 case)	Very Low	Medium

Table 6b: Risk Assessment for the Impact of Identified Risk Factors on the Likelihood of Abortion in Asian Elephants in European Zoos.

Risk Factor	**Supported by Peer Reviewed Papers**	**Supported by Questionnaire Results**	**Risk Assessment**	**Uncertainty**
Stress	10	-	Low	High
Age of Cow	57	No	Low	Medium
Primiparous Cows	57	No	Low	Medium
Reproductive Pathology	38	No	Low	Medium
Salmonella	-	No	Negligible	Medium

Table 7a: Risk Assessment for the Impact of Identified Risk Factors on the Likelihood of Dystocia in African Elephants in European Zoos.

Risk Factor	**Supported by Peer Reviewed Papers**	**Supported by Questionnaire Results**	**Risk Assessment**	**Uncertainty**
Primiparity	-	Statistically Significant	High	Low
Separation of Cow from other Elephants	40	Trend	High	High
Management System (No Contact compared to Free Contact)		Statistically Significant	High	High
Obesity	60	-	Medium	Medium
General Stress	8,10,40	-	Medium	High
Stress from Chaining Cow	8,10,40	No	Low	Medium
Excessively Large Calves	11,35	No	Low	Medium
Position of Calf	-	No	Low	Low
Age of Cow at Parturition	13	No (Statistically proven)	Low	Low
Reproductive Pathology	31,32,34	No	Low	Medium
Oedema	-	No	Low	Medium
Hypocalcaemia	-	-	Low	Low
Reproductive Monitoring	19,32,34,54	No	Low	Low
Twins	54	No	Very Low	Low

Congenital Abnormality of Calf	23	No	Very Low	Low

Table 7b: Risk Assessment for the Impact of Identified Risk Factors on the Likelihood of Dystocia in Asian Elephants in European Zoos.

Risk Factor	**Supported by Peer Reviewed Papers**	**Supported by Questionnaire Results**	**Risk Assessment**	**Uncertainty**
Separation of Cow from other Elephants	1, 8, 24,19,36,40,	Statistically Significant	High	Low
Position of Calf	43,61,63	Statistically Significant	High	Low
Excessively Large Calves	10,11,36	Statistically Significant	High	Low
Management System (Free compared to Protected)		Statistically Significant	High	High
Stress from Chaining Cow	8,10,19,36,40	No	Medium	High
Primiparous Cow	13	Trend	Medium	Medium
Obesity	60	-	Medium	Medium
General Stress	8,10,40	-	Medium	High
Age of Cow at Parturition	13,19	No	Low	Low
Reproductive Pathology	31,32,34	No	Low	Medium
Oedema	-	No	Low	Medium
Hypocalcaemia	61,53,55	-	Low	Low
Reproductive Monitoring	19,32,34, 54	No	Low	Low
Twins	54, 57	No	Very Low	Low
Congenital Abnormality of Calf	55	No	Very Low	Low

Table 8a: Risk Assessment for the Impact of Identified Risk Factor on the Likelihood of Stillbirth in African Elephants in European Zoos.

Risk Factor	**Supported by Peer Reviewed Papers**	**Supported by Questionnaire Results**	**Risk Assessment**	**Uncertainty**
Dystocia	-	Statistically Significant	High	Low
Primiparity	-	Trend	Low	Low
EEHV	_	No	Low	Low
Cow Pox	_	No	Low	Low

Table 8b: Risk Assessment for the Impact of Identified Risk Factor on the Likelihood of Stillbirth in Asian Elephants in European Zoos.

Risk Factor	**Supported by Peer Reviewed Papers**	**Supported by Questionnaire Results**	**Risk Assessment**	**Uncertainty**
Primiparity	39, 46	Statistically Significant	High	Low
Dystocia	39,46	Statistically Significant	High	Low
EEHV	30,55,61	Yes	High	High
Cow Pox	65	No	Medium	Low

Table 9a: Risk Assessment for the Impact of Identified Risk Factors on the Likelihood of Poor Maternal Behaviour in African Elephants in European Zoos.

Risk Factor	**Supported by Peer Reviewed Papers**	**Supported by Questionnaire Results**	**Risk Assessment**	**Uncertainty**
Primiparous Cow	-	Trend	High	Medium
Lack of Experience of Calves	14,59	No	Medium	Low
Separation from Other Elephants at Birth	8,62	No	Medium	High
Chaining of Cow at Birth	8,62	No	Medium	High
Maternal Aggression	52,	No	Low	Low
Aggression from Other Herd Members	52	No	Low	Low

Placentitis/Metritis	-	No	Very Low	Low
Maternal Agalactia	-	No	Very Low	Low

Table 9b: Risk Assessment for the Impact of Identified Risk Factors on the Likelihood of Poor Maternal Behaviour in Asian Elephants in European Zoos.

Risk Factor	**Supported by Peer Reviewed Papers**	**Supported by Questionnaire Results**	**Risk Assessment**	**Uncertainty**
Primiparous Cow	46,60	Statistically Significant	High	Low
Lack of Experience of Calves	59	Significantly Significant	High	Low
Separation from Other Elephants at Birth	8,19,46,62	No	High	Medium
Chaining of Cow at Birth	8,19,46,62	No	High	High
Maternal Aggression	46,52,60	No	Low	Low
Aggression from Other Herd Members	46,52,60	No	Low	Low
Placentitis/Metritis	-	No	Very Low	Low
Maternal Agalactia	39	No	Very Low	Low

Table 10a: Risk Assessment for the Impact of Identified Risk Factors on the Likelihood of African Elephants in European Zoos Failing to Rear a Calf to 5 Years Old.

Risk Factor	**Supported by Peer Reviewed Papers**	**Supported by Questionnaire Results**	**Supported by Studbook Evidence**	**Risk Assessment**	**Uncertainty**
Failed Handrearing		Yes	Yes	High	Low
Separation from Mother <5 Years of Age	8,9,24	-	Yes	High	Medium
Separation of cow from other elephants at birth	8,62	No	-	Medium	High
Chaining of cow at birth	8,62	Trend	-	Medium	High
Inter-calving Interval	-	-	Yes	Medium	High
Primiparous Cow		Trend	-	Medium	Low
Lack of Maternal Experience	14	Trend	-	Medium	Low

Herd Stability	5,21,26,62,64	No	-	Low	Medium
Infanticide		No	-	Low	Low
EEHV	30	No	-	Low	Low
Killed by Other Elephant (Not Mother)		No	-	Low	Low
Other Infectious Disease	-	No	-	Low	Low

Table 10b: Risk Assessment for the Impact of Identified Risk Factors on the Likelihood of Asian Elephants in European Zoos Failing to Rear a Calf to 5 Years Old.

Risk Factor	**Supported by Peer Reviewed Papers**	**Supported by Questionnaire Results**	**Supported by Studbook Evidence**	**Risk Assessment**	**Uncertainty**
Failed Handrearing	18	Yes	Yes	High	Low
Primiparous Cow	39, 46,60	Statistically Significant	-	High	Low
Lack of Maternal Experience	59	Statistically Significant	-	High	Low
EEHV	30,55	Yes	Yes	High	Low
Herd Stability	62,65	Statistically Significant	-	High	Medium
Separation from Mother <5 Years of Age	8,9,24,	Yes	Yes	High	Medium
Separation of cow from other elephants at birth	8,19,46,62	Trend	-	Medium	Low
Chaining of cow at birth	8,19,46,62	No	-	Medium	Low
Infanticide	46,52,60	No	-	Low	Low
Killed by Other Elephant (Not Mother)	46,52,60	No	-	Low	Low
Other Infectious Disease	39	No	-	Low	Low
Inter-calving Interval	39	-	No	Low	High

Discussion

This risk assessment provides ranked lists of factors that influence each stage of reproduction in captive European elephants. It builds on previous studies by combining multiple data sources in a framework which facilities comparison between the peer-reviewed literature and primary data from the specific target population. This is important as much of the peer-reviewed literature is focused on other populations of elephants such as the North American zoo populations, timber camp elephants or wild elephants. There are significant demographical and management differences between these populations and the under-studied European captive elephant population.

For some risk factors both the peer-reviewed literature and questionnaire results are based on a very small number of case reports. These include factors such as twinning, congenital deformities and cases of infectious diseases. Theses risk factors occurred rarely and so were assessed of being very low to low risk and with a low uncertainty.

Examining the first risk pathway, the assessment suggests that in Asian elephants the age of the cow and reproductive pathology are the primary risk factors for both acyclicity and failure to conceive. These two risk factors are linked as older cows are more likely to develop reproductive pathology. These issues have been well studied (Brown et al, 2004; Freeman et al, 2004, Freeman et al, 2010) however in the North American population, Asian elephants appear to be likely to continue cycling normally with reproductive tract pathology (Brown et al, 2004b) but in this study only 35% of the cows with reproductive tract pathology were cycling normally therefore avoiding development of the pathology or attempting to treat it could reduce the risk of acyclicity.

In African elephants very different risks were found to be of significance. In the African elephants there is an association between acyclicity and females being maintained at the same facility with the same herd mates for a long period of time. There are several examples of non-cycling females that resumed cycling either after a transfer or alteration of herd dynamics however there are also cases of cycling females become

acyclic after similar changes (Freeman et al, 2009). There are an increasing number of studies that show that changes in herd composition by the introduction of new animals can have positive effects on social behaviour whilst stress associated with the move is neither prolonged or severe (Dathe et al, 1992; Schmid et al, 2001; Laws et al, 2007; Fanson et al, 2013). This suggests that in non-reproductive herds a transfer of animals may be a justifiable method to attempt to stimulate reproduction.

The amount of exposure to daylight has been reported as positively influencing reproductive cycles (Schulte, 2000) and disputed by others (Brown & Lehnhardt, 1997). In this study the acyclic animals of both species had at least 50% less access to daylight than cycling animals. This is an important area for further research.

In both species restricted access to a bull was considered a risk factor. In zoos the access of cows to bulls is often restricted for a number of reasons, with some zoos not housing a bull (Mason & Veasey, 2010). It is possible that the restrictive management of herds in zoos does not allow conception to occur because during the most fertile period, the cow and bull have been separated. When a cow's reproductive cycle is around 16 weeks and therefore she only cycles approximately 3-4 times per year this can have significant impact on conception rates. In the wild, bulls will stay with family groups when a cow is in oestrus continually monitoring her status and indeed the receptive females may move away from the herd maintaining close contact with the male and soliciting him with specific visual and olfactory signs (Poole & Moss, 1989). In one study, pregnancy rates were greatly enhanced when cows were left with the bull 24 hours a day (Olsen et al, 1994).

Our study has highlighted the importance of elephant social structure and learnt behaviours and how the inevitable restriction of these in captivity can impact on reproductive behaviour.

It is not known to what the extent that the cues and behaviours associated with of detection of oestrus are learnt. Many zoo elephants have not been exposed to cycling cows or adult bulls during their adolescence and therefore some infertility may be due to lack of experience or the lack of an opportunity to learn of either cows or bulls (Rees, 2004). Without bulls in the herd young females grow up not knowing how to behave

towards bulls and might remain frightened of them for the rest of their lives (Garai & Kurt, 2006).

In the wild, adolescent males (10-20 years of age) are very sociable and associate with older males providing the opportunity to lean from more experienced individuals (Evans & Harris, 2008). This is supported by Rees (2004) who proposed that the development of normal sexual behaviour in juvenile bulls may depend on exposure to reproductively active adults.

It is known that in the wild cows prefer to mate with older bulls greater than 35 years old (Ortolani et al, 2005). In the European population there are relatively few older bulls but a wide age range of cows.

Conception failure can of course be caused by infertility of the bull. This must be differentiated from the bull not having the social or behavioural knowledge to mate the cow successfully. This would require specialist reproduction examinations (Hildebrandt et al, 2000b).

We have used the risk assessment findings and our expert working groups to produce evidence based recommendations for further research and management changes which could improve reproductive success in European zoo elephants.

Table 11: Summary of the Risk Factors Assessed as Highly Influencing Likelihood of Conception in European Zoo Elephants and Proposed Mitigating Actions.

Step in Risk Pathway	Species	Risk Factors	Potential Actions
Acyclicity and Failure to Conceive	Asian	Age and Reproductive Tract Pathology	Manage cows to breed when younger. Assess and treat reproductive tract pathology, where appropriate in an attempt to start cycling again.
Acyclicity	African	Lack of change in social group	Consider inter-zoo transfers in herds which have not changed in composition and are non-reproductive.
Acyclicity	Both	Restricted access to daylight	Further research needed but increase access to natural daylight. Use special roofing on houses which does not restrict UV.
Access to Bull	Asian	Access to bull restricted overnight and to periods when cows considered to be in oestrus.	Design facilities to allow unrestricted access and manage animals so access is unrestricted and the elephants can chose to be together.
Access to Bull	African	Incompatible behaviour between cows and bulls, no bull housed and access to bulls restricted.	Ensure all potential reproductive cows are housed with a bull. Manage elephants to encourage affiliative behaviours and provide opportunities for elephants to learn

			social behaviour from peers.
Failure to Mate	Both	Lack of bull choice	Build elephant facilities which can house multiple bulls and allow fission-fusion herd structures.
Failure to Mate	Both	Young age of bull	Provide opportunities for young bulls to learn reproductive behaviour by managing multi-bull facilties.
Failure to Mate	African	Cow or bull refuses to mate.	Manage elephants to encourage affiliative behaviours and provide opportunities for elephants to learn social behaviour from peers.
Failure to Conceive	Asian	Unproven bull	Examine bulls to ensure fertile. Manage elephants to encourage affiliative behaviours and provide opportunities for elephants to learn social behaviour from peers.

Examining the second risk pathway, in African elephants little previous work on captive births could be identified and therefore the survey results formed the majority of the evidence. This found the causes of dystocia to be varied with only separation from other elephants at the time of parturition being considered a high risk factor. In contrast consistent findings were identified in Asian elephants, which were that older, primiparous cows are considered more likely to suffer from dystocia. In Asian elephants calf birth weight was also consistently found to be significant.

The questionnaire survey generated new information on the impact of calf presentation on the likelihood of dystocia as the literature only describes individual case reports. It is possible that the position of the calf is associated with an increased calf weight as large calves may be less able to change position in the uterus.

In contrast to previous studies, the risk of aggression and infanticide from dams to calves was shown to be low. This may be due to the greater proportion of zoo born cows which are reproductively active and have maternal or allomothering experience, which was found to be very important in reducing poor maternal behaviour and improving calf survival.

In both species, separation from other elephants and, in Asian elephants, chaining at the time of parturition was found to be high risk factors for dystocia. In Asian elephants both these factors were also found to be high risk factor for poor maternal behaviour and calf survival. These assessments were based on statistically significant survey results supported by weak literature evidence. These risk factors require further investigation in order to develop elephant management best practice.
In Asian elephants herd instability was found to be a high risk factor for calf survival. This risk factor is very important as it has consequences for management decisions regarding the movement of incompatible cows out of breeding herds to improve social wellbeing.

Clubb et al (2008) found a strong association between removal of a calf from their mother before three years of age and a failure to survive. In African elephants this was not supported. However in Asian elephants, the study indicated that the mortality rate of calves removed before they are five years old is double the mortality rate of calves who are removed after they are five years old.
The devastating impact of Elephant Endotheliotropic Herpes on captive virus is demonstrated by this study.

Table 12: Summary of the Risk Factors Assessed as Highly Influencing Likelihood of Rearing a Calf to Five Years Old in European Zoo Elephants and Proposed Mitigating Actions.

Step in Risk Pathway	Species	Risk Factors	Potential Actions
Dystocia	Both	Separation of Cow from other Elephants	Do not separate cows for births
Dystocia	Asian	Stress from Chaining Cow	Do not chain cows for births
Dystocia	Asian	Older, primiparous cows	Encourage breeding when young
Dystocia	Asian	Excessively Large Calves	Evidence poor but consider diet management.
Dystocia	Asian	Position of Calf	Veterinary monitoring so preparations can be made for a potential dystocia.
Poor Maternal Behaviour	Both	Lack of Experience of Calves	Manage elephants to encourage affiliative behaviours and provide opportunities for elephants to learn social behaviour from peers particularly maternal behaviour and allomothering experience.
Poor Maternal Behaviour	Asian	Separation from Other Elephants at Birth. Chaining of Cow at Birth	Do not separate or chain elephants for births.
Failure to Rear Calf to 5 years Old	Both	Failed Handrearing	Avoid handrearing whenever possible by managing other risk factors.
Failure to Rear Calf to 5 years Old	Asian	Separation of cow from other elephants	Do not separate or chain elephants for births.

		Chaining of Cow at Birth at birth.	
Failure to Rear Calf to 5 years Old	Both	Lack of Maternal Experience	Manage elephants to encourage affiliative behaviours and provide opportunities for elephants to learn social behaviour from peers particularly maternal behaviour and allomothering experience.
Failure to Rear Calf to 5 years Old	Asian	Herd Stability	Manage elephants to facilitate herd stability. Consider moving uncompatible elephants out of a herd to increase stability.
Failure to Rear Calf to 5 years Old	Asian	Separation from Mother <5 Years of Age	Do not separate calves from mothers – maternal lines are essential for developing normal herd structure. If elephants must transfer the whole maternal line should be moved.
Failure to Rear Calf to 5 years Old	Asian	EEHV	Continued research and treatment protocols should be developed.

Conclusions

This study aids in the identification of the most significant risk factors to reproduction and by association, welfare in the European captive zoo elephant population. By providing a structured and transparent assessment of the complex and often conflicting evidence combined with new data from the population, the study allows

prioritisation of actions to mitigate these risks. This study begins to address previously recognised differences in the causes of reproductive failure between the European captive elephant population and other populations that have hindered the production of specific and appropriate management recommendations in the past.

The study defines the importance of promoting and supporting the development of broad social experience and expression of natural behaviours in elephant management practices. The challenges of space and resources influence the practicalities of this but further emphasis should be paced on managing multi-maternal line herds and multiple bulls in facilities, which promote fission-fusion behaviours allowing bull choice, elephants to avoid each other during times of conflict or stress and elephants to learn social skills. This in turn will lead to a more natural age structure of the European zoo elephant population.

The findings of this study have been presented to the Elephant Taxon Advisory Group of the European Association of Zoos and Aquaria who manage and supervise the European zoo elephant population who are using this work as evidence to support current management recommendations, to modify existing husbandry guidelines and a means of highlighting research priorities. The work is a component of a broad review of elephant welfare in the United Kingdom, which will contribute to revision of the zoo licensing system.

The work has highlighted some key areas for further research which are being investigated in further studies. These include evaluating the importance of learnt social behaviour in bulls, assessing compatibility and herd instability and the impact of daylight on reproductive cycles.

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Chapter 10 – Discussion and Conclusions:

10.1 Risk Analysis as a Tool for Decision Making:

The work introduced in Chapter 1, and evidenced in Chapters 2-9, relates to the use of risk analysis as a tool for evidence-based decision making. The concept of evidence-based decision making has evolved from its roots in evidence-based medicine. Evidence-based medicine integrates clinical experience, patient values, resources available and research information into decision making (Masic, Miokovic & Muhamedagic, 2008). Evidence-based decision making was given significant momentum when it was placed at the core of the Modernising Government White Paper in 1999 (Cabinet Office, 1999), which called for policies that were proactive, innovative and shaped by evidence rather than political ideology or prejudice. This instigated the adoption of 'Evidence-based Policy Making' by the British Government. As evidence-based policy was implemented, it was identified that government funded research was not related to greatest need, was ad-hoc, often poorly conducted and driven by scientists rather than practitioners, managers or policy makers (Peckham, 1991).

To address these failures in government research, commissioning approaches have been adopted that prioritise research, assess the best evidence available, collate findings from multiple sources and present them in a way that is accessible and relevant to decision makers (Tranfield, Denyer & Smart, 2003). This led to an expansion of the use of not only traditional scientific research, but also applied sciences (Parsons, 2002), including social science research and economic studies, such as cost-benefit analyses. This allowed the focus issue to be considered in the context of resources, culture, values, impact and public acceptance (Gray, 2004).

Risk analysis is an applied science discipline (Carrington & Bolger,1998), capable of using evidence from a wide range of sources and of differing quality. As such, it is more likely to meet the risk managers' needs for information and decision support than a traditional 'pure' science analytical process (Aven, 2012; Carrington & Bolger, 1998)

and is therefore particularly useful for evidence-based decision making and policy approaches.

10.1.1 Wildlife Health

My work to develop the England Wildlife Health Strategy comprehensively demonstrates evidence-based policy making (Hartley and Lysons, 2011). This paper, presented in Chapter 6, is unique in that it sets out the national policy approach to wildlife disease risks and explains how the policy was developed thus, contradicting consistent criticism of the lack of transparency in government policy making (Relly & Sabharwal, 2008). The paper is also significant as it focuses and explains approaches to risk management and risk communication, which are neglected in the literature therefore describing how technical information is used to define policy.

In my work, in Chapter 6, risk analysis is highlighted as an important tool in a comprehensive approach to risk detection, assessment, prioritisation and mitigation, alongside disease surveillance (Lysons, Gibbens & Smith, 2007), geographical information system and data assessment tools (Paiba, Roberts, Houston el al, 2007), risk prioritisation approaches (Vilas, Voller, Montibeller et al, 2013) and expert panels, all of which are used as an evidence base for animal health decision making and policy development in the United Kingdom. In response to my review and development of a structured, systematic, risk-based approach to wildlife health policy, a range of significant outcomes were achieved under my directorship (Hartley & Lysons, 2011 and see Chapter 6). Wildlife disease surveillance was enhanced through the foundation of the UK Wildlife Disease Surveillance Partnership. I led a revision and modernisation of import policies for wildlife (Hartley & Roberts, 2015 - see Chapter 2), I wrote specific chapters for wildlife species, which were included in national contingency plans for exotic notifiable diseases (Hartley, 2010; Hartley, Voller, Murray & Roberts, 2013- See Chapter 5) and disease risks were included in the approval of conservation interventions licensed by government (Hartley & Gill, 2010 – see Chapter 4).

Several of my studies were directly commissioned for government policy making purposes and are rare examples of full risk analyses, including risk communication (which publication is a key component) and risk management actions. This

demonstrates my breadth of experience and expertise as both a scientific risk analyst and a policy maker by integrating technical, political, social and ethical issues into the work. Furthermore, I assessed the risk of the introduction of rabies via the import of zoo animals (see Chapter 2: Hartley & Roberts, 2015). This was used as the basis for amendments to The Rabies (Importation of Dogs, Cats and Other Mammals) Order 1974, which included reducing rabies quarantine periods from six to four months and ensuring consistency in policy for zoo animal imports. This study was scrutinised by international disease experts and the European parliament to ensure robustness. Furthermore, national disease contingency plans for exotic notifiable diseases have been expanded to describe disease management actions, should disease be identified in wild animals, based on two of my risk analyses (Chapter 5: Hartley, Voller, Murray & Roberts, 2013; Hartley, 2009). The contingency plans are laid before parliament and subject to both technical and political challenge. The accuracy of the risk analysis and effectiveness of the changes made are yet to be challenged as there have been no disease outbreaks since publication. In Chapter 4, I presented my work on the management of disease risks from interventions licensed under the Wildlife and Countryside Act (1981) (Hartley & Gill, (2010). This provides further demonstration of the use of risk analysis concepts in the delivery of transparent and evidence-based public policy. The risk-based approach encourages a proportionate level of restrictions on conservation interventions controlled by licensing therefore addressing a potential source of introduction of disease into free-ranging wildlife.

10.1.2 Zoo Animal Health and Welfare

Evidence-based decision making concepts are being adopted by many industries and scientific disciplines as diverse as business management, education and economics (Tranfield, Denyer & Smart, 2003). This has included the fields of wildlife conservation (Sutherland, Pullin, Dolman & Knight, 2004) animal welfare (Dawkins, 2006), zoo animal management (Melfi, 2009) and zoo animal welfare (Barber, 2009). Common to many other areas of science, these papers provide discussion on how evidence-based decision making has the potential to be used in wildlife conservation and zoo management, but there are very few published examples of how the approach has been used and delivered practical outcomes. To address this, I have championed the adoption of risk analysis as an evidence-based approach to decision making in zoos through three of my studies presented in this thesis.

In Chapter 7 (Hartley, Grove, Lewis, Beeston & Stewart, 2014), I demonstrated an evidence-based framework for epidemiological disease investigation in zoos. This work resulted in the lifting of restrictive disease controls and alleviating the need for culling of animals. In Chapter 8 (Hartley & Schmidt, 2013), I provide an example of a full risk analysis for decision making regarding disease in zoo animals, which addressed significant concerns regarding animal health and zoonotic disease risks. The risk analysis allowed effective communication to zoo managers and halted unnecessary euthanasia of infected animals. A disadvantage of this work is that the assessment of the impact of SIV as 'negligible' has resulted in laboratory testing and further research being of low priority hindering further investigation of the issue.

The work in this thesis has provided the basis for evidence-based disease management guidelines for the European Endangered Species Management Programme; for example, in Hartley (2016; see Chapter 9, I used risk analysis to assess risk factors for reproductive failure and associated welfare impacts in elephants. The outcomes of my research were presented to the European Association of Zoos and Aquarias' (EAZA's) Taxon Advisory Group, and consequently my findings influenced development of best practice standards in European zoos. In the UK, my study was used to modify the requirements of the Zoo Licensing Act (1981) as set in the Secretary of States Standards of Modern Zoo Practice increasing best practice standards for elephant care in UK zoos.

10.1.3 Risk Analysis as an Adaptive Management Tool

The ability for risk analysis to be adaptive and modified as new evidence becomes available make the techniques especially useful for policy and decision making. Newly published peer-reviewed papers, new grey literature (such as surveillance data or disease control data following a recent outbreak) or revised expert opinion can easily be fed into the same process and the risk analysis be modified. Alternatively, factors influencing risk perception and appetite may require policy to be reviewed. This could be due to changing values regarding ethics, welfare and public acceptability or political priorities. These issues played an important role in the need for policy review described in my work on rabies, presented in Chapter 2 (Hartley & Roberts, 2015).

A further advantage of risk analysis is that, if it is used to aid decision making, that decision or policy can be implemented and data collected from monitoring the outcome. This data can be used to review and assess the success of the decision. If the risk analysis process is transparent and clear when published and not modified, population with data from post-decision monitoring provides a robust and repeatable tool for impact assessment. The risk analyses in Chapters 2 and 5 could be used in this way.

The series of papers based on my work, which I have presented in this thesis, demonstrate that risk assessment can provide an adaptable, flexible approach to systematically reviewing, collating and collecting evidence for decision making in wildlife and zoo animals. Risk assessment should be seen as a tool for representing and expressing the knowledge and lack of knowledge available (Aven, 2012) and used with the caveat that decision making under risk and uncertainty should be risk–informed and not risk-based.

10.2 Evidence for Risk Analysis:

In order to undertake a comprehensive risk analysis, a wide variety of information is required which often presents a challenge. This means that data from a wide range of sources, collected for many different primary purposes and of varying quality, will be required to assess the risks effectively. As in evidence based medicine, risk analysis practitioners must develop skills in efficient literature searching, application of formal rule of evidences, systematic reviews, meta-analyses which identify multiple relevant studies and evidence sources and critically analyse them (Masic, Miokovic & Muhamedagic, 2008).

In my papers in Chapter 2: Hartley & Roberts (2015) and Chapter 8: Hartley & Schmidt (2013), information for the risk assessment was extrapolated from the minimal literature on the specific scenario and then from peer-reviewed publications on other species and in different circumstances. A limitation of these two assessments is that there was no appropriate grey literature available. Retrospectively, the lack of evidence is unsurprising as the likelihood of the scenarios being studied occurring was

concluded to be very low or negligible. Therefore, as the events are so rare there will have been very few opportunities to collect relevant information historically.

In Chapter 3: Hartley & Sainsbury (2017) I explain that when assessing disease risks relating to wildlife disease, data on the species and populations of animals will be required, as well as data on pathogens in the source and destination populations, mechanisms of spread, potential impact, non-infectious hazards and preventative health procedures, such as quarantine and pathogen screening. Beyond this, broader information on the ecosystem, such as natural barriers, habitat, climate and vegetation type may also be important, as these factors will influence epidemiology and, consequently, the disease risk. However, in reality many risk analyses are compromised by the lack of such data, or the lack of expertise to process and integrate it into the risk assessment.

The study I led, to investigate disease risk in free ranging deer (Hartley, Voller, Murray, & Roberts, 2013; see Chapter 5), presents a clear example of how these factors can be integrated into risk assessment and, in particular, ecology and behaviour, which are historically absent from previously published analyses. In this assessment, peer reviewed literature was supported by a range of wildlife disease surveillance information obtained from the UK wildlife disease surveillance programme and the OIE wildlife disease surveillance programme. Deer population sizes and distributions were provided from wildlife management organisations and habitat data from published datasets. In addition, data were obtained from an experimental infection study being undertaken prior to its outcomes subsequently being published (López-Olvera, Falconi, Férnandez-Pacheco, et al, 2010). This combination of diverse and wide ranging data sources, the engagement of specialist data analysts to process the data and inclusion of confounding factors, such as behaviour and ecology beyond the epidemiology of the potential pathogens, sets this risk assessment as a model for best practice.

I again demonstrated the combination of multiple data sources in my studies on elephant reproduction (Chapter 9; Hartley, 2016), Peer-reviewed literature was used to determine the causes of reproductive failure, i.e. the release assessment. The exposure assessment was determined from frequency of the defined causes of

reproductive failure reported in peer reviewed and grey literature. As a defined population was under investigation, more specific approaches were possible as numerical data could be extracted from the European elephant studbook allowing semi-quantitative anlaysis which can be considered more robust. This study went further and used specific data for use in the analysis. A questionnaire was used to generate data for the study, and data were analysed statistically and published in a peer- reviewed paper (Hartley & Stanley, 2016). This allowed the robustness of the study to be challenged twice by peer-review once for the questionnaire study and again for the risk analysis itself thus helping to address the accusation of poor quality science discussed in Chapter 1.

10.2.1 Use of Experts and Stakeholders

As risk assessments are often undertaken to analyse specific scenarios and published information of wildlife health and welfare is limited, knowledge gaps can be addressed by engaging with individuals and collecting their evidence as described in Chapter 1.

Experts provide technical information about the hazards, the system (animal, habitat, process) or identified confounding factors, whilst stakeholders are those who will be affected by the risk question. As such, stakeholders will influence likelihoods of the release and exposure assessments through their actions and behaviours. They will also be able to advise directly on the consequence assessment, as the consequence will have direct impact on them personally (see Chapter 6: Hartley & Lysons, 2011). A significant omission in the risk analysis literature is that it fails to recognise the essential role of stakeholders. Stakeholders may not have technical expertise on the hazards or the risk assessment, but provide essential contribution to the risk management and risk communication components of the risk analysis (Hartley & Gill, 2010 - See Chapter 4; Hartley & Lysons, 2011 – See Chapter 6; Hartley et al, 2013 – See Chapter 5). Stakeholder engagement is essential in any decision-making process, and stakeholders were engaged in all of the studies included in this thesis enhancing their relevance and utility for decision makers. In reality, individuals are often likely to be both experts and stakeholders, or experts in multiple aspects of the risk assessment, especially small, specialised niche fields such as wildlife health and welfare. This lack of distinction requires that the information required from individuals is clearly defined and collected in a transparent and as objective manner as possible

The decision of when and how to use expert opinion will depend on the nature of the information required, and if these variables are impacting at the risk analysis or risk management stages of the risk assessment. Parameters where a lack of empirical knowledge is impeding the analysis should be prioritised (Martin et al., 2012). It should be predetermined what information is required, how it will be fed into the risk assessment process and how the opinions will be elicited (Burgman, 2001; Krueger et al., 2012). This will indicate whose opinion or judgement is needed and their area and level of expertise.

Expert and stakeholder opinion or judgements can be used at several different points in the risk analysis process. For example, in Hartley & Schmidt (2013; see Chapter 8), we used engagement of primate virology experts to assist in development of the risk pathway and my expert knowledge was used to formulate the risk management and risk communication components of the risk analysis, which required understanding of zoo management and operations. Chapter 10; Hartley (2016) used expert opinion in an alternative way as a workshop was used to identify and investigate the confounding factors which drove the risk pathway rather than collecting information on the hazards themselves. In Hartley & Roberts (2015) and Hartley and others (2013), experts reviewed the risk assessment after it has been constructed and were used as a challenge function prior to entering the risk management stages of the process (Fletcher, 2005; Jakob-Hoff et al., 2014; Krueger, Page, Hubacek, Smith, & Hiscock, 2012). Opinions may also be sought during development of the risk management and communication as in Hartley & Gill, (2010), and Hartley & Lysons (2011), where stakeholders were specifically targeted so that the impacts of the decision making on those affected by the outcome could be fully considered and therefore increasing the likelihood of the policy being supported by them .

In my studies, where resources were available, expert and stakeholder input was obtained using workshops, which have the significant advantage of allowing discussion, debate and challenge between participants, and for facilitators to estimate consensus within the group which generates important information regarding certainty in the risk assessments (Jakob-Hoff et al, 2014; Wieland, Dhollander, Salman & Koenen, 2011). A weakness in the series of papers in this thesis is that, although

evidence was obtained through structured questioning, no specialist elicitation techniques such as the Delphi technique or multi-criteria decision analysis were used. This has the potential to introduce bias and subjectivity. The main reason specialist techniques were not used was the lack of experience by the analysts, including myself. A further methodological weakness is that the source of the evidence collected was not presented clearly in any of the risk analyses so that information obtained from experts and stakeholders is not directly identifiable from that obtained from other sources. This reduces the transparency of the evidence base and influences the levels of uncertainty in the analysis.

10.3 Risk Analyses can be Adapted to Different Scenarios:

The complex interactions of wildlife species and their environments, in the wild or captivity, pose challenges for risk analysts (Jakob-Hoff et al, 2014). This requires that the generic framework for risk analysis described in Chapter 1 may need to be adapted, modified or developed to facilitate analysis.

10.3.1 Hazard Identification

Hazard identification can be a significant problem when assessing disease risks in wildlife and zoo animals due to the limited understanding of the epidemiology and pathogenicity of many infectious agents. Previous definitions of a hazard require an infectious agent to cause harm (Murray, 2004). Sainsbury & Vaughan-Higgins (2012), modified the definition to so that the novelty of an infectious agent to the host is a sufficient reason to classify the infectious agent as hazardous in the absence of information on pathogenicity. This approach has been adopted as best practice and therefore was used in my series of studies in this thesis (Chapter 4: Hartley & Gill, 2010; Chapter 5:Hartley, Voller, Murray & Roberts, 2013) and endorsed in my paper describing methodological approaches to the use of risk analysis in conservation (Chapter 3: Hartley & Sainsbury, 2017).

A significant challenge when working with some risk questions is that the number of potential hazards can become very large. For example, Neimanis & Leighton (2004) identified 122 potential pathogens associated with translocation of wild Eastern

turkeys *(Meleagris gallopavo).* Criteria can be established for ranking the importance of each hazard and its possible direct and indirect consequences, within the bounds of the defined risk question in order to manage this. Alternatively, the prioritisation could be achieved through an initial risk process using a set of defined criteria, before undertaking a full assessment. Examples of this are provided in Chpater 3 (Hartley & Sainsbury, 2017). A range of independent tools using multi-variable models and bespoke software to prioritise diseases have been developed, which could be used to assist in hazard identification for wildlife disease risk assessments (Ciliberti, Gavier-Widén, Yon, Hutchings, & Artois, 2015; Tavernier, Dewulf, Roelandt, & Roels, 2011; Vilas et al., 2013). These methods must then allow transparent justification of the hazard selection.

Often the risk question and the needs of the risk manager will assist in prioritising the diseases that should be included in the risk assessment. The processes and justification for government interest in wildlife diseases are explained and justified in Chapter 6 (Hartley & Lysons, 2011). These principles are then adopted in the risk analyses described in Hartley (2010) and Chapter 5 (Hartley et al., 2013), which clearly define the hazards of interest to the risk managers, in this case government ministers. The hazards of primary interest to the risk manager may well vary from those identified by scientific specialists, as they will need to address ethical, societal and resources issues. These factors must be included in prioritisation approaches.

10.3.2 Risk Pathways

Traditional risk assessment has been criticised for having a narrow focus, only assessing one hazard at a time and not addressing how different hazards may combine to affect health and welfare, or how human and animal behaviour may affect these risks. In domestic animal import and incursion disease risk analysis, developing the risk question will result in two different scenarios. Firstly, the problem could be focused on a single risk pathway, but involves multiple hazards, for example risks posed to consumers of legally-imported cooked chicken from outside of Europe (Oscar, 1998). In this case, the legal import is a single pathway and potential pathogens in the chicken being the multiple hazards. In contrast, the problem could be specific to one well-defined hazard and there are multiple risk pathways, for example rabies (the single hazard) entering the country in domestic dogs (which may

come in through legal and illegal routes and from different origins) (Jones, Kelly, Fooks, & Wooldridge, 2005).

A simple risk pathway very rarely occurs when considering risks posed by wildlife and zoo animal health issues. Import disease risk assessment, as advocated by the OIE, uses international borders as the division between source and destination environments and thus limits the possibility of hazard release and exposure (Murray et al, 2004; Chapter 2: Hartley & Roberts, 2015). In contrast, wild animals and their parasites are restricted in their distribution by ecological barriers (e.g. niche separation) and topographic barriers (e.g. mountain ranges or seas), rather than political barriers, and this must be reflected in the risk assessment which has been ensured where relevant in my work (Hartley, 2010; Chapter 5: Hartley et al, 2013; Sainsbury & Vaughan-Higgins, 2012). The ecology and behaviour of the target species and other animals (including humans) in the environment must be considered in the risk pathways, as the contact rates, associations and subsequent disease transmission will be influenced by these factors (Hartley, 2010; Chapter 5: Hartley et al, 2013).

My research in the papers in this thesis has led to the development of techniques for working with multiple hazards and multiple risk pathways in a single risk analysis (Hartley, 2010; Chapter 8: Hartley & Schmidt, 2013; Chapetr 5: Hartley, Voller, Murray, & Roberts, 2013, Chpater 2: Hartley & Roberts, 2015, Chapter 9: Hartley, 2016). My work is innovative in that they develop the recognised risk analysis techniques to include multiple species, multiple diseases and multiple risk factors in a single assessment and then apply these techniques to two different environments, free-ranging wildlife and zoo animals. The important influencing factors of animal behaviour, social structure and ecology are integrated into the assessments further broadening their application and reflection of complex nature of natural systems.

10.3.3 Tools for Risk Analysis

The risk assessment can be developed using a wide range of additional tools, ranging from simple diagrams and spreadsheets to more clearly present the data, to bespoke software which develops quantitative assessments using data collected, to complex

models that explore variability and uncertainty. A comprehensive review of available risk assessment tools is presented by Jakob-Hoff et al. (2014). The use of these tools does not divert from the risk analysis framework, but merely contributes to enabling risk conclusions to be reached and justified. In this series of papers, two of the more basic tools were used as described below.

Scenario trees are graphical models that identify the stages in the risk pathway (release, exposure, consequence) and can show confounding risk factors involved in driving the risk pathway. Thus, these visual pictures provide a useful conceptual framework for the risk assessment, facilitate transparency and aid in communicating the risks to the various stakeholders, in a simple, logical and reasoned framework (Hatfield & Hipple, 2002; Macdiarmid & Pharo, 2003). In the series of papers presented in this thesis, the scenario tress have developed from abstract simplified process maps, as in Chapter 2 (Hartley & Roberts, 2015), to more illustrative representations of the biological pathways being investigated and highlighting each risk factor analysed, as used in Chapetr 9 (Hartley, 2016). This presentation of the risk pathway supports understanding of the risk analysis by non-technical audiences and, when used alongside risk tables (see below), allows risk conclusions to be clearly placed in context to the biological pathway being analysed. This detailed use of scenario trees with confounding risk factors is unique to this series of papers.

To ensure utmost transparency and to aide development of the risk assessment, a risk table is a useful tool. This is particularly true where multiple hazards and multiple risk pathways occur. A risk table shows the steps in the risk pathway, summarises evidence, states the release, exposure and consequence assessment and produces a final risk estimation for the hazard or pathway (Hartley, 2010; Chapter 5: Hartley et al, 2013; Jakob-Hoff et al, 2014). The inclusion of detailed risk tables is particularly well demonstrated in Chapter 9 (Hartley, 2016) where the tables expand on the information displayed in the scenario tree and specifically indicate the source of evidence on which the risks have been assessed.

A further very useful tool for wildlife risk analysis is to extend the assessment spatially using geographical data sets, which can be presented in Geographical Information Systems (Jackson et al, 2009). This was used in Chapter 5 (Hartley et al., 2013) to

map habitat, deer populations and livestock populations to assess disease transmission risks.

10.4 Quantitative or Qualitative Risk Assessments?

All the risk analyses in this series presented the risk assessments qualitatively. There were several reasons for this. Firstly, in all the scenarios investigated there was a significant lack of data, particularly numerical data. This meant that although limited amounts of numerical data were available no complete risk pathway could be fully populated, and so no complete quantitative analysis could be completed. The challenges of attempting quantitative risk assessment with poor data have been recognised, as models based on incomplete or inappropriate data cannot be validated and rely on mathematical assumptions rather than a knowledge of biology and therefore result in a wide variation in??? risk estimates (Carter, 1991; Hardman & Ayton, 1997).

Quantitative assessment could have been completed if resources and time were available to commission bespoke data collection to generate numerical data. This was only possible for the study presented in Chapter 9 (Hartley, 2016). In other scenarios, either resources to fund additional data collection were not available or the risk manager required the risk analysis to be delivered to deadlines which did not allow additional evidence generation therefore only qualitative risk assessment was possible.

It could be argued that qualitative approaches were more appropriate in all the risk assessments in the series as they included multiple risk pathways and the initial risk question required assessment of relative risks to develop risk management strategies. A useful secondary exercise would be to select individual, simple risk pathways from the scenario trees and re-assess the risk using quantitative techniques as a pre-intervention baseline and then repeat this after the risk management actions had been implemented to provide an indication of the success of the policy change.

An additional argument for the use of qualitative approaches is that quantitative risk assessment cannot account for a difference between technical consequences and the consequences of societal values (Fletcher, 2005) as a numerical value is almost impossible to assign cultural or ethical concerns. In qualitative risk analysis, scientific risks can be presented alongside cultural, public opinion and communication risks, giving decision makers an overview of the broader risks associated with the scenario (Hanisch-Kirkbrid et al., 2013). This is especially beneficial in the development of government policy where ministerial decisions may ultimately be determined by politics rather than science (Hathaway, 1991). In these qualitative risk analyses it could be argued that the assessment of risk is less important than communicating the arguments underlying the assessment and the reasons for making judgements (Aven, 2012; Fletcher, 2005; Hardman & Ayton, 1997).

Interpretation of quantitative presentation of risk requires expertise. In these scenarios, the risk analysis was commissioned for risk managers without understanding of quantitative risk determination, which can lead to numerical values being mistaken for highly precise outcomes (Hardman & Ayton, 1997; North, 1995)

The use of semi-quantitative techniques is controversial, with the advantage over a well-researched, transparent, peer-reviewed qualitative approach in adversarial situations being questioned (Bruckner et al, 2010). My series of risk analyses, in this thesis, did lend themselves to application of semi-quantitative techniques. In all the assessments, small amounts of data were available or could have been calculated. In addition, expert and stakeholder opinion could have been collected using structured methods to generate scores or weightings. The comprehensive use of scenario trees in this series is particularly useful as numerical values could be applied to individual stages and risk factors. Semi-quantitative techniques can improve objectivity if the numerical values are assigned transparently, consistently applied and care is taken in calculating statistically probabilities. The major justification for not using semi-quantitative techniques for these studies is the risk analyst's lack of experience and expertise in quantitative techniques and lack of access to relevant software. This lack of skills and experience could have compromised the risk assessments by introducing conclusions that are statistically and logically incorrect (Jakob-Hoff et, al, 2014).

10.5 Dealing with Uncertainty:

As discussed in Chapter 1, risk analyses must deal with uncertainty that comes from a lack of evidence, interpretation of the evidence and variability in biological systems (Carrington & Bolger, 1998), all of which are highly relevant to wildlife health and welfare. Despite this, uncertainty is poorly addressed and often not incorporated into risk assessments particularly when qualitative methods are used (Carrington & Bolger, 1998; Slooten, Fletcher & Taylor, 2000). In quantitative risk assessments, modelling techniques such as Monte Carol analysis and Bayesian decision analyses can be used to calculate probability distribution (Carrington & Bolger, 1998; Harwood, 2000). There are multiple reasons for this, firstly because describing or quantifying uncertainty when numerical probabilities are not being calculated is challenging to develop a methodology that is transparent and has meaning. Secondly, because each step of a multiple risk pathway has its own uncertainty therefore a method must be developed to combine them. Finally, because acknowledging uncertainty could undermine the risk manager's confidence in the risk analysis (Carrington & Bolger, 1998).

In an attempt to address this deficit, the risk analyses in the papers presented in Chapters 2, 5, 8 & 9 included a subjective estimate of uncertainty. I took into account the volume and quality of evidence and differences of expert and stakeholder opinion. Uncertainty was reflected by a descriptive rank that, for consistency, used the same terminology and risk matrix as the risk assessment. This uncertainty assessment was reflected in in the risk tables. This was a novel concept in the field of wildlife and zoo based qualitative risk assessment and has not been published elsewhere.

10.6 The Future Use of Risk Analysis in Wildlife Health and Welfare:

The series of published papers examines the use of risk analysis techniques in eight wildlife and zoo animal health scenarios. The papers have subsequently been used to guide policy development and decision making at a national, European and wider international level demonstrating the value of risk analysis as a tool to assess and present evidence in a structured and scientifically valid method. Risk analysis provides

a framework flexible enough to maintain scientific rigour whilst ensuring effective communication of the outcomes.

Very few animal health (MacDiarmid, 2000) or wildlife disease (Jakob-Hoff et al, 2014) risk analyses have been published in peer-review literature and even fewer studies of evidence-based decision making in wildlife and zoo health and welfare. Where papers have been published they often only state that a risk assessment was completed and forms the basis of the study, but it is not presented (for example, Stephens et al. 2013) In contrast, this thesis contains a significant number of the complete risk analyses published in peer-reviewed journals and attempts to address the lack of accessible material to assist in developing the discipline through transparency, knowledge transfer and to allow decision makers to become familiar with risk analysis techniques. The work in this thesis has identified opportunities to develop the use of risk analysis in the field.

10.6.1 Development of expertise

One of the key strengths of risk analysis is that, once the principles and framework of the methodology is understood, it can be undertaken by scientists who are not deep statistical or modelling specialists. This allows risk analysis to be used by project teams that do not have access to specialists and limited resources. In all these scenarios in this thesis, as a wildlife health and welfare scientist, was the lead risk analyst the risk analysis but also the risk manager. Several stages of the risk analysis process could be improved if I was trained in specialist techniques, including those to extract evidence from experts in a structured way, the use of a broader range of risk analysis tools, semi-quantitative or quantitative techniques and modelling of uncertainty. The advanced training of wildlife health scientists and decision makers should be facilitated.

10.6.2 Evidence Sources

I used risk tables (See Chapters 2, 5, 8 & 9) to present the risk assessments made at each stage in the risk pathway. The references for the peer-reviewed papers that contributed to these risk assessments were included in the tables and further justification summarised in the text, however the transparency and objectiveness of this assessment could be improved by adding a summary of the other evidence

sources and the extent of their contribution in reaching this assessment. This is partly included in the corresponding uncertainty assessment, but could be numerically represented, for example a percentage of the contribution of peer-reviewed, grey literature, expert opinion and specific data. Appendices stating how expert and stakeholder evidence was elicited, the questions asked and a structured report could be included to allow readers a complete understanding of how the assessments were reached.

10.6.3 Elicitation of Expert and Stakeholder Opinion

The choice of experts and stakeholders, and the reason for their inclusion, should be recorded and categorised to transparently demonstrate any potential bias and difference in representation of interests. Again, a scoring system could be developed to be included in uncertainty calculations.

There is growing interest in the use of formal, structured and moderated processes for elicitation of expert opinion (Krueger et al., 2012; Wilson, 2017) and these tools should be reviewed and integrated into qualitative risk assessment in the future in order to address the issues of bias and accuracy. Although recognised techniques such as the Delphi techniques or behavioural aggregation could be used, simply by developing scoring systems for assessing consensus, recording the number of experts who agree with each assumption or stage in the risk pathway and how confident they are in their assessment would significantly increase the value of the opinions in assessing risk and uncertainty.

10.6.4 Quantitative and Semi-Quantitative Risk Analysis

Further effort needs to be made to develop quantitative risk assessment approaches into wildlife health and welfare risk analysis when the limitations described in this thesis can be overcome. More realistically, semi-quantitative assessments could be integrated into specific risk pathways. It has been recommended that all risk analyses should first be attempted qualitatively (Vose, 2008) and then if expertise, resources and data are available a quantitative analysis can be built on (Peeler et al, 2007). In order for risk analysis in wildlife health and welfare to develop to the same level as other fields, such as environmental management and food safety, the use of quantitative methodologies must be progressed.

10.6.5 Tools

The integration of a wider range of the tools described by Jakob-Hoff et al. (2014) should be adopted and used to assess risk more frequently. By developing these techniques, the objectivity and transparency of the outputs will be improved. They would be particularly useful in scenarios where comparative risk must be assessed, facilitating a more quantitative approach to be adopted.

The use of GIS data sets in wildlife risk analysis is under-used. By over-laying habitat, population, climate and other relevant data and statistically calculating risk criteria and interdependencies, risk can be presented in a geographical context, which has significant advantages to assessing impacts and planning mitigation measures.

10.6.6 Uncertainty

The assessment of uncertainty should be developed further to be more objective. As modelling will not be possible unless quantitative techniques are used, an alternative would be to use transparent and structured, criteria based scoring systems for the sources of evidence and information elicited from experts as described.

10.6.7 Resources

Evidence-based decision making in wildlife health and welfare is compromised by chronic lack of resources. In disciplines such as public health, food safety and environmental protection, where risk analysis is valued as an irreplaceable tool for decision making, risk communication and public policy, significant investment has been made in training specialised analysts and data collection to feed into established risk analysis methodologies. If the wildlife and zoological practitioners are to fulfil their aspirations to be able to justify decisions using science rather than anecdote, then investment must be made in prioritised scientific study, to generate evidence and monitor the impact of interventions and education of technical experts and decision makers in the use of scientific methodologies that facilitate decision making, such as risk analysis.

10.6.8 Application

Risk analysis methodology has considerable potential to contribute to the developing field of wildlife welfare assessment, as demonstrated by my work in this thesis. Epidemiological studies, such as risk analysis, are recognised as an effective way to identify the interactions of the environment and management factors that can lead to welfare problems and identify areas for improvement (Barber, 2009; Carlstead et al., 2013). It has been recognised at the European level that there is a need to develop a formal approach to risk analysis for animal welfare (European Food Safety, 2006a) which was realised by the assessment of the welfare of intensively reared calves (European Food Safety, 2006b). A critique of this specific assessment identifies that, whilst a useful approach, improvements in hazard definitions, collation of expert opinion, assessment of uncertainty and transparency of underlying data would increase robustness (Bracke, Edwards, Engel, Buist, & Algers, 2008). These are all issues that I have considered in this thesis and proposed approaches to addressing them. The field of wildlife welfare could be significantly advanced by the use of risk analysis techniques.

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